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RECENT COURT JUDGEMENT ON SEXUAL HARASSMENT OF WOMEN AT WORKPLACE

CASE HISTORY

The petitioner was working as an Assistant Director with ESI Corporation in Manesar, Gurgaon in July 2011. On 8th July 2011, the petitioner made a written complaint to the Director-General of ESI Corporation alleging sexual harassment by Respondent No.3 (R-3). According to the petitioner, (R-3) misbehaved and made attempts of sexual advances [Para 2].

Respondent No.1 (R-1) constituted an internal complaints committee to examine the complaint of the petitioner. R-3 appeared before the committee and denied all the allegations made by the petitioner. According to R-3, the petitioner made the complaint because of the grudge against him due to certain official work disposed of by him in her absence [Para 3].

The committee examined the petitioner as well as R-3. The committee examined eight witnesses. namely: O.S., Supervisor Housekeeping, Rajender Yadav (SSO), Prasanna (Staff Nurse), Hema (Staff Nurse) Pradeep Kataria (Nursing Orderly), Jai Bhagwan (Nursing Orderly) and Kalpana (Dietician) [Para 4].

COURT JUDGEMENT

Ref: *J. R. Midha, J. Anita Suresh vs. Union of India & Ors., W.P.(C) 5114/2015,*
Date of Judgment: 09.07.2019. Delhi High Court.

No witness out of eight supported complainants. On careful consideration of the record of the inquiry proceedings, this Court is of the view that the complaint dated 8th July 2011 of the petitioner appears to be false. The complaint dated 8th July 2011 contains two incidents out of which the first incident was in the presence of the petitioner's colleagues whereas the second incident was in the presence of the staff and other members. During the inquiry proceedings, the petitioner could not give the name of any person present at the time of the incidents.

The petitioner was shown the record of the staff persons present on duty on the date of the incident but still, she could not recollect the names of any colleague/staff member. It is not believable that the petitioner would not remember the names of any colleague/staff member. The committee examined all the persons who were on duty on that day but no persons supported the allegations of the petitioner. The petitioner has not mentioned the alleged comments of respondent No. 3 in the complaint on the ground of modesty. The petitioner did not even disclose the alleged comments before the committee. No reason or justification was given by the petitioner for not disclosing the same before the committee. The entire complaint of the petitioner appears to be false and has been filed with some ulterior motive. Past service record shows that the petitioner did not have a clean service record. Delhi High Court concluded that there is no merit in this writ petition which is dismissed with cost of Rs. 50,000/- to be deposited by the petitioner with the Delhi High Court Advocates Welfare Trust within four weeks. [Para 19] Respondent No. 2 is at liberty to initiate appropriate action against the petitioner for filing a false complaint against the respondent No. 3 under law [Para 20].

Expert Comment:

Abuse of law should not be allowed in the larger public interest and to protect honour and dignity of alleged accused. The illegal, arbitrary and perverse, mala fide, complaints of sexual harassment at workplace in abuse of law and ultra vires the Constitution of India and the Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act, 2013.

GUEST EDITORIAL

COVID-19: is there an end in sight

Bhattacharyya NC*

In a recent report in the journal *Cell*, a team of investigators of Los Alamos National Laboratory led by Bette Korber et al. suggested that 614G, the latest variant of SARS-CoV-2 virus is responsible for the increasing global transmission of COVID-19. It was also reported that the main reason for the higher rate of transmission is that the mutated virus replicates faster in the upper respiratory tract in the human body, thus increasing the viral load in the infected individuals. It has also been observed that this does not increase the case severity, but certainly increases the infectivity.¹

Although the outbreak of an influenza-like illness caused by a new coronavirus in Wuhan, China was reported as early as December 2019, the World Health Organization (WHO) took a considerably long time to declare it as a Public Health Emergency of International Concern only on January 30, 2020, and also to declare it as a new epidemic under the name of COVID-19 on 11 February, 2020.² Consequent to this there has been widespread criticisms from various countries regarding the role of WHO in containing COVID-19, as WHO declared it as a Global Pandemic as late as on 11 March, 2020.³ By that time alarm bells have started ringing across the globe as the disease has already spread to many countries of the world.

The rapid spread of the disease during February and March 2020 across several countries of Europe and other continents led to research about the mode of transmission. Initially thought to be from droplet infection at close contact with an infected individual, other routes of spread are also being investigated. Scientists from different countries of the world have suggested that airborne transmission of micro-droplets which may persist in a close environment in the form of aerosol for a longer time and may spread up to a distance of several meters may be one of the probable cause of the faster rate of spread of SARS-Cov-2 virus, and adequate control measures must be taken in this direction.⁴ They have expressed the opinion that changes in the physical environment in the workplaces, markets and departmental stores, gyms, places of worship, educational institutions, hospitals and clinics with physical distancing and adequate ventilation of the premises will be essential soon.

How the present pandemic is likely to progress is a matter of speculation. But our experience of similar events may offer some insights into the future. Perhaps we will have to learn to live with the disease; the most recent example of this in the history of the world was the Spanish Flu caused by H1N1 influenza virus pandemic of 1918-20.⁵ Another pandemic in 1957, caused by H2N2 virus removed whatever was remaining of the previous pandemic. As some experts have put it in the right way, "What Nature can do it, we cannot".⁵ SARS epidemic of 2003 caused by a coronavirus, was fortunately limited to a few countries because of very aggressive efforts of containment. This was thought to be possible because most of the people infected by the virus had serious symptoms and they transmitted the virus only after getting sick. But with SARS-CoV-2 the situation is different. Here persons infected by the virus have a wide spectrum of clinical presentations, from totally asymptomatic cases to mild, moderate and severe illness with respiratory distress, bilateral lung consolidation, cytokine storm, DIC like picture and death. Fortunately, the percentage of asymptomatic cases and persons with mild influenza-like illness is quite high; but at the same time, they continue to spread the virus before becoming symptomatic, or even before becoming positive on swab test. This is the reason for the rapid spread of the disease despite the global efforts for containment, with the imposition of lockdowns, and various other methods like social distancing, use of masks and hand hygiene.

The last few months in the history of COVID-19 has seen the evolution of a standard treatment of the disease. In the initial period of the pandemic, there was a lot of confusion regarding the use of drugs like hydroxychloroquine and azithromycin. Gradually a clear picture emerged regarding the pathophysiology of the disease process and these drugs are no longer accepted in the treatment module. The role of steroids to stabilize the excessive immune response as evidenced by the rise in IL-6 was widely discussed and accepted as a part of the standard treatment regime. Also, the role of low molecular weight heparin to combat intravascular coagulation was established. Antivirals like

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Remdesivir is now used in many centres routinely. To combat cytokine storm, monoclonal antibodies like Tocilizumab is now being increasingly administered with good results. High flow oxygen therapy essentially remains the primary treatment once the oxygen saturation starts falling. Improvement in the ICU care with ventilation has also contributed to the lowering of the case fatality ratio. The latest addition to the armamentarium is convalescent plasma therapy. In a systematic review of several publications in PubMed, EMBASE and Medline databases up to April 2020, Rajendran et al., concluded that convalescent plasma therapy (CPT) may reduce mortality in critically ill Covid-19 patients by increasing the neutralizing antibodies, clearance of the virus, and beneficial effect on the clinical symptoms.⁶ Li et al. (June 2020) published their first report of a randomized clinical trial of convalescent plasma therapy in 7 medical centres in Wuhan, China, where they concluded that convalescent plasma therapy added to the standard treatment compared to standard treatment alone did not result in a statistically significant clinical improvement. This study was prematurely terminated because of non-availability of the required number of severely sick patients, as the epidemic was already on the decline in Wuhan by that time.⁷ More research is necessary to establish the role of CPT in the treatment of severe COVID-19 cases.

The previous SARS outbreak in 2003 caused by a closely related coronavirus may have slowed down because of mutation. This is Nature's way of controlling the epidemic. In case of SARS-CoV-2, the recently reported change in the amino acid at position 614 of spike protein from aspartic acid (D) to glycine (G) has caused the emergence of the 614G variant which is the prevalent strain now.¹ The mutated strain is reported to be more infective, although increased ability to infect a cell line in the laboratory does not necessarily mean increased infectivity in the human body or the community as a whole. However, scientists all over the world are worried about the SARS-CoV-2 virus not undergoing enough mutations as expected at the beginning of the outbreak. Perhaps there is not enough influence of natural selection, as the virus is racing through the continents in millions of non-immunized people with very little resistance.⁸ Probably an effective vaccine will be the only answer, which hopefully may force it to evolve into a less infective variant.⁸

Meanwhile, the incidence of COVID-19 has rapidly declined in the country of its origin (China). Those countries of Europe which had devastating effects of the disease in February and March 2020 are already showing the decline in the incidence of new cases and also in the mortality. In countries like the USA, India and Brazil, the pandemic is currently showing a rising curve, although the death rate is now significantly lower than that in the initial period of the disease, probably due to improvement in the standard treatment regime.

Case Fatality Ratio (CFR) is an important way of assessing the severity of an epidemic. It generally refers to the total number of reported deaths divided by reported cases on any

particular point of time.⁹ This is in contrast to Infection Fatality Rate (IFR), which is the number of reported deaths divided by the total number of infected cases (including the reported as well as the unreported cases). In the case of Covid-19, IFR is almost impossible to compute because the actual number of infected cases is not known as a large number of infected people are either asymptomatic or not tested, and therefore hidden in the community. Even CFR is also not a correct measurement, as, for the number of deaths occurring up to a certain point of time, the corresponding number of patients were infected a variable period of days ago. This lag period is observed to be different from country to country. An average lag period may be calculated which can be taken into account while estimating the CFR, and this is called LagCFR, which is more close to reality.¹⁰ Wilson et al. has calculated an average lag period of 13 days from confirmation of the diagnosis to the day of death.¹¹ According to the authors, this gives a more realistic view of the case fatality during the epidemic. For example, in the Indian scenario, the total number of deaths due to COVID-19 till 19 July 2020 was 27,503; and the corresponding number of confirmed cases till this date was 11,18,780. Hence the CFR on this date was 2.49. However, if we take the average lag time from initial diagnosis (hospitalization) to the date of death to be about 2 weeks, then the lag case fatality rate (LagCFR) will be 3.94, as the total number of confirmed cases on 5 July 2020 was 6,97,836.¹² Thus if we do not consider the lag period, it gives us a false idea of a low fatality rate, particularly with the incidence of confirmed positive cases on a rising curve. Once the curve reaches a plateau, this difference between CFR and LagCFR will get minimized, and we will have a more realistic figure. With the rapid improvement in technology and availability of diagnostic facilities in the country, particularly after the introduction of rapid antigen testing kits and TrueNat equipment, the number of tests done in India has crossed 19 million by the end of July 2020. During this time, the number of confirmed test positive cases exceeded 1.6 million.¹² Fortunately, the majority of the test positive cases are asymptomatic or mildly symptomatic. The opinion is gradually building up in the country whether the asymptomatic and mild cases can be quarantined at home, thereby making available scarce hospital beds for the moderate, severe and critically sick cases in an already highly stressed health care system in the country.

In India, the disease started spreading only from the middle of March 2020. Initially, the spread was slow, which was thought to be due to the timely intervention by the government in the form of nationwide lockdown. The unprecedented displacement of the migrant population in the aftermath of lockdown was probably the biggest disaster in the history of independent India. It not only produced extreme hardships to the life of millions of poor people but also helped in spreading the disease to the nook and corners of the country. In our country, prolonged lockdowns are bound to inflict untold miseries to the poor section of the population. Ultimately the choice between life and livelihood stares in the

face of the common people, and they gradually start getting desperate to have their livelihood restored.

How does a pandemic like COVID-19 end? There are only a few possibilities. In the absence of an effective and specific antiviral therapy, we have to expect that an effective vaccine will be available in the earliest possible time. Epidemiologists hope that sooner or later a mutation will occur with which the virus is going to lose its 'Sting'. In the natural course of the disease, herd immunity will take a very long time to develop, and until it develops there will be a lot of sufferings to mankind. There is a fourth possibility of "Social end" of the pandemic when the people, in general, will be no longer afraid of the disease and they will learn to live with COVID-19.

The Oxford COVID Vaccine Trial Group has published the initial report of phase 1/2, single-blind, randomized controlled trial of ChAdOx1nCoV-19, which showed an acceptable safety profile, increased antibody response, and T-cell immune response against SARS-CoV-2.¹³ This is an encouraging report, perhaps the first of many more similar efforts currently being undertaken in various other research centres across the world. On the other hand, Ibarrondo et al. reporting from University of California School of Medicine, Los Angeles has cautioned against "immunity passports", herd immunity, and perhaps vaccine durability in light of their finding of short-lived immunity against human coronaviruses, as their findings suggested rapid decay of IgG antibodies in mildly symptomatic Covid-19 patients.¹⁴

Initial reports of ongoing research work on an effective vaccine against SARS-CoV-2 are pouring in from several other countries including India, USA, China and Russia. These are reported to be in the advanced stage of human trials. Hopefully, by the end of the year 2020, the events will take a turn for the better. Until then, we have to accept social distancing, masks and hand hygiene as part of our life and hope for the best.

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ORIGINAL RESEARCH PAPER

Clinicopathological profile of patients with up-front metastatic breast cancer: a study from North East India

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ABSTRACT

Introduction: Breast cancer is the most common cancer in Indian females and approximately 5-10% present with up-front metastasis and 20-30% patients develop metastasis during follow up, but still limited data is available regarding the same. **Objectives:** To study the clinicopathological profile of breast cancer patients presenting with up-front metastasis. **Materials and methods:** This is a retrospective study of Metastatic Breast Cancer (MBC) patients who attended the Medical Oncology Department of State Cancer Institute, Guwahati. In the study, we reviewed the records regarding clinical and histological profile, receptor status and site of metastasis of breast cancer patients presented with up-front metastasis from January 2019 to December 2019. **Results:** Total of 65 cases of MBC were studied. The average age of presentation was 46 years (range 22-70 years) with an average duration of symptoms 8 months (range 3-18 months). Male and Female ratio was 2:63. MBC was common in post-menopausal (52.38%) and Para 2 (48.7%) women. 41.53% of patients were at performance status 1 at presentation. In the histopathological study, ductal carcinoma was the most common (93.85%) pathological type with Nottingham grade II (60%) was the most common. Baseline receptor status suggested that 56.92% were hormone receptor [HR] positive, 40% were human epidermal growth factor-2 [Her2] neu positive and 18.46% were triple-negative breast cancer [TNBC]. Various sites of metastasis were visceral only (20%), bone (40%), combined bone and visceral (36.92%), non-regional lymph nodes (15.38%) and brain (4.61%). **Conclusion:** MBC is common in younger patients with bony metastasis being the commonest site of metastasis. **Keywords:** Histopathological profile; receptor status; sites of metastasis.

INTRODUCTION

Breast cancer is one of the earliest known malignancies of mankind documented way back in 6th century as “Divine punishment”.¹ Now in the 21st century breast cancer has become the most commonly occurring cancer in women both in developed and developing countries like India and the second most common cancer overall. According to GLOBOCAN 2018 statistics, there were over 2 million new cases of breast cancer in 2018 worldwide.² The incidence of breast cancer is increasing in the developing countries due to increased life expectancy, increased urbanization and adoption of western lifestyles. Indian Council for Medical Research [ICMR] reports 1.5 lakh new breast cancer cases in India per year. As reported in the Western literature,³ approximately 5-10% of patients present with up-front metastasis and 20-30% of patients develop metastasis during follow up. The scenario is quite different in India with approximately 5-25% breast cancer patients still present in metastatic stage.⁴ An average age of 50-53 years is reported for breast cancer patients in various population-based studies done in India.^{5,6} Breast cancer is considered to be a systemic disease because it can metastasize to distant sites in early stages even before

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the primary tumour become clinically evident so the management approach and treatment strategy directed only to the primary tumour will not be sufficient. The management and prognosis of breast cancer are largely based on luminal classification i.e. molecular subtype, HR [ER and/or PR] and /or Her2neu status of the patient, visceral versus non-visceral metastasis, performance status [PS] and age of the patient. Hormonal therapy, targeted therapy and chemotherapy are the various modes of treatment apart from surgery, radiotherapy depending on patient profile. Targeted therapy will be more beneficial if we know the receptor targets and if the patients present at an early stage of the disease. State Cancer Institute, Guwahati is one of the tertiary care oncology centres of North Eastern region of India providing comprehensive oncology services to the patients from entire NE regions however data regarding the MBC patients is still limited from this part of the country. With the knowledge from the existing literature, we have aimed to evaluate the clinical and pathological characteristics of our breast cancer patients presenting with up-front metastasis so that it gives us an idea of the clinical spectrum of MBC patients from this part of the country and the pathological and molecular profile of these patients which would imply the treatments and outcomes.

MATERIALS AND METHODS

The present study is a hospital-based retrospective study carried out on 65 breast cancer patients attended Department Medical Oncology at State Cancer Institute, Guwahati presenting with features of up-front metastasis during one year period from January 2019 to December 2019.

During the study periods, 389 breast cancer patients were registered in the OPD services of State Cancer Institute, Guwahati. Out of these, 73 patients presented with up-front metastasis and 65 patients were considered for analysis and 8 patients were excluded because of incomplete medical records or lost to follow up after 1st visit.

We retrieved the data regarding patient's characteristics [age, sex, menopausal status, PS and duration of symptom], pathological features, receptor status [ER/PR/Her2neu], molecular subtype (**Table 1**) and metastatic profile by reviewing the patient's file from the medical records department.

Table 1 Luminal classification [Molecular subtypes] of breast cancer⁷

	Luminal A/B	Her2 enriched	Basal type	Luminal/ Her2
ER/PR expression	+	±	-	+
Her2 amplification	±	+	-	+

Abbreviations: ER, estrogen receptor; PR, progesterone receptor; Her2, human epidermal growth factor receptor 2. Menopausal status is assessed from clinical history as the

permanent cessation of menstrual periods, i.e. when a woman has not had any menstrual bleeding for a year without any other obvious pathological or physiological cause.

Performance status is assessed using Eastern Cooperative Oncology Group performance status [ECOG PS] grading as shown in **Table 2**.

Table 2 ECOG PS⁸

Grade 0	Fully active, able to carry on all pre-disease performance without restriction
Grade 1	Restricted in physically strenuous activity, but ambulatory and able to carry out work of light and sedentary nature
Grade 2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of working hours
Grade 3	Capable of only limited self-care, confined to bed or chair more than 50% of working hours
Grade 4	Completely disabled. Cannot carry on any self-care. Confined to a bed or chair
Grade 5	Dead

HR and Her2neu status was tested by standard immunohistochemistry [IHC] methods. IHC testing was performed in the paraffin-embedded breast tissue blocks [true cut or excisional biopsy specimen] stained with monoclonal antibodies. Allred scoring system was used for reporting the HR status. Allred or H score of 3 or more was considered as positive.⁹ Her2neu status was tested as per the American Society of Clinical Oncology [ASCO] guidelines.¹⁰ A score of 3+ was considered positive and 2+ was considered equivocal and 1+ as negative. All 2+ results of her2neu were confirmed by fluorescence in situ hybridization [FISH] amplification. Histologic type and grade were assessed according to the World Health Organization [WHO] standard and Nottingham grading respectively.¹¹ A metastatic workup was done using ¹⁸F-NaF bone scan, CT scan of thorax and abdomen, magnetic resonance imaging [MRI] of brain or FDG positron emission tomography [PET] CT scan. Bone only, visceral [lung, liver, adrenal], brain and non-regional lymph nodes [LN] were recorded for the site of metastasis. Patient with 5 or fewer metastases involving 1 or 2 organs is considered to have the oligometastatic disease.

RESULTS

The median age of presentation was 46 years [range, 22 to 70 years] and the median duration of symptoms was 8 months [range, 3-18 months]. The male-female ratio was 2:63. MBC was common among postmenopausal women [N=33, 52.38%]. 7 patients [11.11%] were nulliparous and 20 patients [31.74%] had a history of use of some form of hormonal contraceptive medication at some part of their reproductive life. 11 patients [16.92%] had a family history of malignancy and 5 of them were specific for breast cancer (**Table 3**).

Table 3 Clinical characteristics of MBC patients

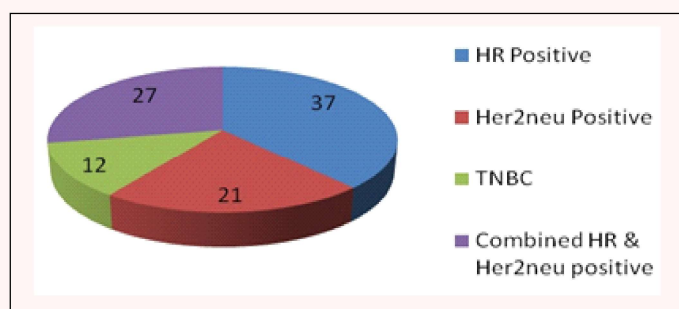
Parameters	Number [%]
Total number of patients Included	65
Median age at presentation (years)	46 years [range, 22-70]
Average duration of symptoms in months	8 months [range, 3-18]
Sex: (n=65)	
Male	2
Female	63
Menopausal status: (n=63)	
Premenopausal	30 [47.62%]
Postmenopausal	33 [52.38%]
ECOG PS: (n=65)	
PS 0	8 [12.3%]
PS 1	27 [41.53%]
PS 2	21 [32.30%]
PS 3	7 [10.76%]
PS 4	2 [3.76%]

Ductal carcinoma was the most common [93.85%] histologic type and Nottingham grade II being the most common grade in MBC patients (**Table 4**).

Table 4 Pathological profile

Parameter	Number [%]
Histologic type	
Ductal Carcinoma	61 [93.85%]
Lobular Carcinoma	3 [4.61%]
Others	1 [1.52%]
Histologic Grade [Nottingham Grade]	
Grade I	3 [4.61%]
Grade II	39 [60%]
Grade III	23 [35.85%]

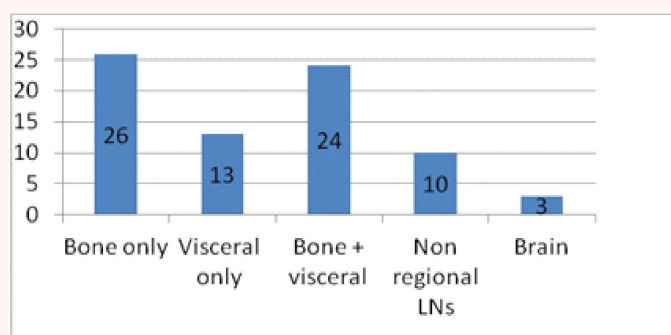
HR status [ER and/or PR] were positive in 37 patients. Her2neu was positive in 21 patients and 12 patients were found to have TNBC (**Figure 1**).

**Figure 1** Baseline receptor status

Abbreviations: HR, Hormone receptor; Her2 neu, Human epidermal growth factor receptor 2; TNBC, triple-negative breast cancer.

The most common site of metastasis was bone [40%], followed by combined bone and visceral metastasis in 36.92%, only visceral metastasis in 20%, non-regional LNs in 15.38% and brain in 3 patients (**Figure 2**). In visceral metastasis, the liver was most frequently involved [60.87%] followed by lung and adrenal.

Overall bony metastasis was the most common site of metastasis irrespective of receptor status. The vertebrae were the most common bone involved by metastasis. 25 patients [38.46%] had the oligometastatic disease. Patients with TNBC presented at an earlier age [37 years, range 22-55 years] and most are premenopausal [66.67%] with poor PS [ECOG PS 2-3] and had multiple sites metastasis at presentation.

**Figure 2** Sites of metastasis

DISCUSSION

Breast cancer is the most common cancer in women worldwide, with the widely variable incidence among countries and regions. As per the ICMR Population-based Cancer Registry data, breast cancer is the most common cancer among women in urban registries and second most common cancer in women after cancer of the uterine cervix in rural registries in India.^{5,6}

In general, breast cancer has been reported to occur a decade earlier in Indian patients compared with their Western counterparts. Although the majority of patients with breast cancer in Western countries are postmenopausal and in their 60s and 70s, the picture is quite different in India, with premenopausal patients constituting approximately 50% of all patients.⁴ More than 80% of Indian patients are younger than 60 years of age. The average age of patients with breast cancer has been reported to be 50 to 53 years in various population-based studies done in different parts of the country.^{5,6} In the present study we have documented a median age of 46 years [range, 22 to 70 years]. In studies from Western countries, the median age of presentation was 55 to 60 years.^{12,13} In our study we found the average age of presentation was 46 years which is almost similar to the study by Gogia A et al.¹⁴ The present study documented that approximately 47.62% of patients were premenopausal and 52.38% were postmenopausal, whereas studies from the

Western world have documented 70% to 80% patients are postmenopausal at presentation.^{12,13}
In this study, HR was positive in 56.92% of patients; previous

studies documented approximately 49% to 68% (**Table 5**). The incidence of TNBC in the present study is 18.46% which is almost similar to the study by Kunikullaya SU et al.¹⁵

Table 5 Comparison of the present study with previous studies

Parameters	Dafni et al ¹²	Giordano et al ¹³	Gogia A et al ¹⁴	Present study
Total no of patients	364	105	375	65
Duration of study	2003-2006	1995-2000	2012-2018	1 year
Age at presentation [years]	60 [27-84]	49 [26-73]	49 [22-80]	46 [22-70]
Menopausal status:				
Premenopausal	19.5%	48%	39.8%	47.69%
Postmenopausal	80%	52%	60%	52.69%
Receptor Status:				
HR positive	68%	49%	61.4%	56.92
Her2neu positive	-	-	38.6%	40%
TNBC	-	-	-	18.46%
Site of metastasis:				
Bone only	50%	28%	26.7	40%
Visceral Only	72.5%	37%	58.4%	20%
Non regional LN	25%	30%	5.6%	15.38%
Brain	-	-	2.7%	4.61%
Combined bone and visceral	-	-	-	36.92%

In patients who had metastasis in this study, 16.71% presented with up-front metastasis. Common sites of metastasis were bone, lung, liver, lymph nodes and brain. Kennecke et al.¹⁶ and Smid et al.¹⁷ in their studies concluded that HR-positive tumours commonly spread to the bone and HR-negative and/or Her2 positive tumours are likely to spread to the viscera; however, in the present study, we have found that bone is a most common site of metastasis irrespective of the receptor status. The liver is the most common site of visceral metastasis [60.7%]. Park et al.¹⁸ in his study found out the correlation between the molecular subtype and pattern of distant metastasis and concluded that Her2 over-expression provide aggressiveness to the tumour and commonly associated with brain metastasis. In the present study, we also found that Patients with visceral and brain metastasis commonly have Her2 enriched MBC.

CONCLUSION

In the study, we have found that the majority of the patients were younger and premenopausal at presentation and in the productive years of their life. Overall receptor status [ER/PR/Her2neu] is positive in 81.54% patients i.e. quite a large number of patients can be treated with curative intent if they present in early stage and can be prevented from developing metastatic disease. Patients with visceral and brain metastasis

is commonly associated with Her2 overexpression so the patients who have her2 enriched tumour at baseline receptors status assessment need special attention during follow up so that early detection of metastasis is possible and targeted therapy can be considered for them. A quite large number of patients in our study presented in a later stage of disease when the performance status was deteriorating indicating that there is a lack of awareness of the disease in the general population.

Limitation of the study: A limitation in our study is that it was a retrospective study and the duration and study population was less so we advocate for further studies with a large number of patients over a larger duration of the period.

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Contribution of authors: (1) The article is original with the author(s) and does not infringe any copyright or violate any other right of any third party. (2) The article has not been published (whole or in part) elsewhere and is not being considered for publication elsewhere in any form, except as provided herein. (3) All author(s) have contributed sufficiently in the article to take public responsibility for it and (4) All author(s) have reviewed the final version of the above

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ORIGINAL RESEARCH PAPER

Histomorphological spectrum of prostatic lesions and their correlation with serum prostate-specific antigen level

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ABSTRACT

Background: Prostate Specific Antigen (PSA) estimation is elevated in patients with prostate enlargements including prostatic diseases, surgical procedures, benign hyperplasia and prostatic malignancy. A significant increase of PSA has been correlated with prostatic cancer and as such the same parameter has been widely used in the diagnosis and management of prostatic cancer. **Objective:** The objective of the study was to determine the relationship between serum PSA levels and histological findings in biopsy specimens of prostatic lesions. **Materials and methods:** This study includes patients planned for prostatectomy. Blood samples were collected preoperatively and tested for PSA. Histology of the tissue samples collected after Trans Urethral Resection of Prostate (TURP) were studied and the relationship with PSA analyzed. The study pertains to the utility of PSA assay in different Prostatic lesions including carcinoma of Prostate. **Results:** 71 patients were included in the study. There were 59(83.10%) benign cases, 7(9.86%) cases of Prostatic Intraepithelial Neoplasia (PIN) and 5(7.84%) cases of Adenocarcinoma (Adenoca) of the prostate. Serum PSA values were analyzed in different prostatic lesions like; Nodular Hyperplasia of Prostate (NHP), High-Grade Prostate Intraepithelial Neoplasia (HGPIN), Adenocarcinoma, etc. **Conclusion:** The study showed a statistically positive correlation between histological diagnosis and serum PSA. In all cases of malignancy, Gleason score was correlated with serum PSA values. However, the present study did not reveal any correlation between the two variables.

Keywords: Gleason's score; carcinoma; prostatitis.

INTRODUCTION

An approach to the diagnosis of prostate cancer has changed

radically in recent years with the introduction of the PSA estimation, by doing an Ultrasound Scan Test (USG) and by Fine Needle Aspiration Cytology (FNAC)/ biopsy of the Prostate.^{1,2}

PSA is a glycoprotein which is secreted exclusively by the prostatic epithelium. It is not a tumour specific antigen as it reacts with the prostatic material in benign and malignant tissues. PSA is expressed in significant quantity by the cancer tissues compared to benign conditions. The normal level values in healthy males are usually <4ng/ml at an average.^{3,4} Serum PSA levels above the reference range have been reported in 50% of the men with stage A prostate cancer, in 80% with stage B disease and 100% with stage C and D disease. In a healthy 60 yrs old man with no evidence of prostatic carcinoma, the serum PSA concentration increases by approximately 3.2% per year (normal average: 0.04 ng/ml). The utilization of age-specific ranges is useful in predicting the survival outcomes in Asian men.^{5,6} The study aims to evaluate histomorphological features of different prostatic

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lesions, classify them in different categories based on morphology and correlate those lesions with serum PSA level, including correlation of prostate-specific antigen levels with Gleason's score in malignant cases.

MATERIALS AND METHODS

The present study is a cross-sectional one. Seventy-one cases of prostatic biopsies received in the Pathology Department of Rahman Hospitals Pvt. Ltd. were included in the study along with their pre-operative serum PSA levels. All the patients who had undergone prostatectomy along with their pre-operative serum prostate-specific antigen levels were included as an inclusion criterion. Whereas non-compliant patient, autolyzed biopsy materials; specimens not properly labeled and cases where serum PSA un-available are excluded from the study.

Biopsy samples were processed for Formalin-Fixed and Paraffin-Embedded (FFPE) technique and stained routinely with Haematoxyline and Eosin (H & E) stain. Special Stains, e.g., Ziehl Neelsen and Mucicarmine were used whenever required.

Specific variables were defined for prostate biopsies during the collection and analysis of the data. Every case was reported by a pathologist and findings were noted for all variables using a proforma. The cases were reviewed by a

second pathologist, wherever indicated. The diagnosis was made using the variables. The diagnosis was then further correlated with the pre-operative serum prostate-specific antigen levels. The estimation of PSA was done quantitatively by a chemiluminescence method. Standard reference values were considered for the age of the patient.

Histomorphological details, histological diagnosis, Gleason score and serum PSA data were statistically analyzed. The distribution of study variables concerning diagnosis was observed and chi-square test and Pearson's Correlation between histological diagnosis and serum PSA levels were analyzed. Results were considered statistically significant if the p-value was less than 0.05.

RESULTS

Seventy-one patients admitted for prostate enlargements were included for the present study. Serum PSA level was estimated in all the cases. Distributions of prostate lesions concerning age and histomorphological features were analyzed and their correlation with serum PSA levels was evaluated in this study.

In this study, out of total cases (N=71); 59(83.10%) cases were benign followed by premalignant and malignant cases comprising of 7(9.85%) and 5(7.04%) respectively.

Table 1 Distribution of different histological diagnosis of prostate (N=71)

Histological diagnosis	Frequency	Percentage	Total	N=71
Benign				
NHP	45	63.38%	59(83.10%)	
NHP with chronic prostatitis	9	12.68%		
NHP with basal cell hyperplasia (BCH)	2	2.82%		
NHP with Granulomatous Prostatitis (GP)	3	4.23%		
Premalignant			7(9.85%)	
HGPIN	7	9.86%		
Malignant				
Adenoca (acinar type)	4	5.63%	5(7.04%)	
Adenoca (mixed acinar and ductal type)	1	1.41%		
Total	71	100%		

The study reveals that out of the total prostate lesions, 45(63.38%) cases were of nodular hyperplasia followed by NHP with chronic prostatitis (9 cases) and high-grade prostate intraepithelial neoplasia comprising of 7 cases. NHP with

granulomatous prostatitis was seen in 3 cases; NHP with Basal cell hyperplasia was seen in 2 cases and Carcinoma Prostate was seen in 5 (7.04%) cases.

Table 2 Distribution of histological variables in benign lesions (n=59)

Histological variables	Present	Absent	Total
Papillary infoldings	56(94.92%)	3(5.08%)	n=59
Cystically dilated glands	56(94.92%)	3(5.08%)	
Corpora Amylacea	46(77.97%)	13(22.03%)	
Basal cells	59(100%)	0	
Basal cell hyperplasia	2(3.39%)	57(96.61%)	
Granuloma	3(5.08%)	56(94.91%)	
Adenosis	34(57.63%)	25(42.37%)	

In this study, among the benign cases (n=59), the most predominant histological variable was basal cells which were seen in all the benign cases. Other variables like papillary infoldings and cystically dilated glands were each seen in 56

(94.92%). Corpora amylacea was seen in 46 (77.97%) cases. Basal cell hyperplasia was seen in 2(3.39%) cases, granulomas were seen in 3 (5.08%) cases and Adenosis in 34 (57.63%) cases.

Table 3 Distribution of histological variables in premalignant lesions (HGPIN) (n=7)

Histological variables	Present	Absent	Total
Nuclear atypia	7 (100%)	0	n=7
Single cell layer	3 (42.86%)	4 (57.14%)	
Central necrosis	2 (28.57%)	5 (71.43%)	
Mitosis	1 (14.29%)	6 (85.71%)	

In this study, nuclear atypia was observed in all cases of HGPIN. Other variables like single cell layer, central necrosis and mitosis were seen in 3 (42.86%), 2 (28.57%) and 1 (14.29%) respectively.

Distribution of histological variables in malignant cases (n=5): Out of 5 cases of carcinoma (n=5), infiltrative glands, single-cell layer, nuclear atypia, mitosis, central necrosis and adjacent PIN were seen in all the 5 (100%) cases. Histological

variables like crystalloids and papillary structure each were seen only in 1 (20%) case.

Distribution of Gleason score in different histological diagnosis (n=5): In this study, out of 5 cases of prostate carcinoma (n=5), Gleason score 6 was more frequently encountered, comprising of 2 (40%) cases, followed by Gleason score of 7, 8 and 9 comprising each of 1 (20%) case.

Table 4 Different histological diagnosis according to different cut-off values of Serum PSA level (N=71)

Histological diagnosis	Serum PSA(ng/ml)			Total
	<4	4-10	>10	
Benign				
NHP	44 (61.97%)	1 (1.41%)		45 (63.38%)
NHP with chronic prostatitis	0	9 (12.68%)		9 (12.68%)
NHP with BCH	1 (1.41%)	1 (1.41%)		2 (2.82%)
NHP with GP	3 (4.23%)	0		3 (4.23%)
Premalignant				
HGPIN	0	0	7 (9.86%)	7 (9.86%)
Malignant				
Adenoca (Acinar type)	0	0	4 (5.63%)	4 (5.63%)
Adenoca (mixed acinar and ductal type)	0	0	1 (1.41%)	1 (1.41%)
Total	48 (67.61%)	11 (15.49%)	12 (16.90%)	71 (100%)

Out of total cases (N=71), serum PSA level <4ng/ml was seen predominantly in NHP followed by NHP with GP and NHP with BCH cases respectively. A serum PSA level of 4-10ng/ml was seen in NHP with CP followed by NHP and NHP with BCH each comprising of 1 (1.41%) cases. Serum PSA level >10ng/ml was seen only in premalignant and malignant conditions; HGPIN (p value < 0.05, χ^2 test).

Correlation between serum PSA and Gleason score (n=5):

In our study, there was statistically no correlation between Gleason score and serum PSA level in all cases of carcinoma (n=5) ($r=-.258$ p-value=0.676).

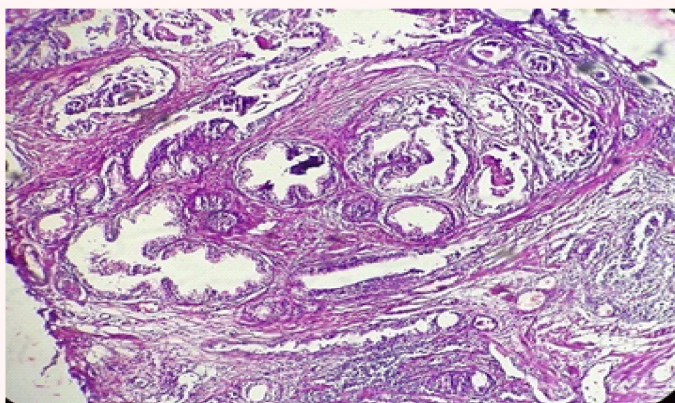


Figure 1 Proliferating acinar cells, intraluminal secretions and chronic inflammatory cells in benign nodular hyperplasia (H & E 100X)

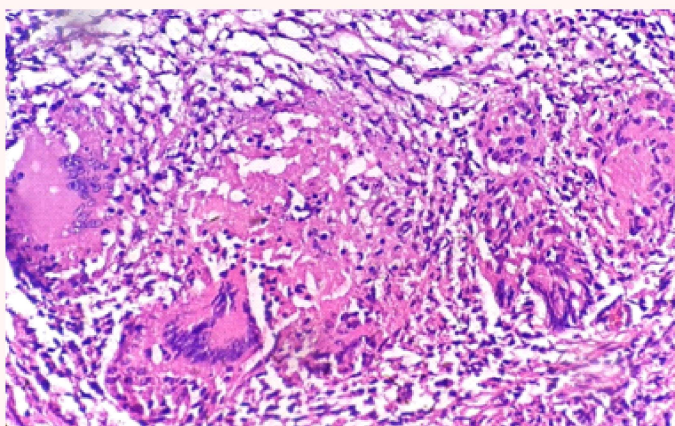


Figure 2 Granulomatous prostatitis (H & EX 400)

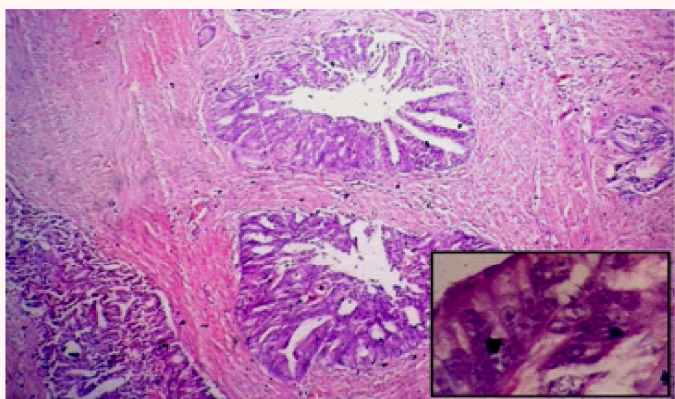


Figure 3 Nuclear stratification in HGPIN (H & E; 100X), Inset- Prominent nucleoli in HGPIN (H & E; 1000X)

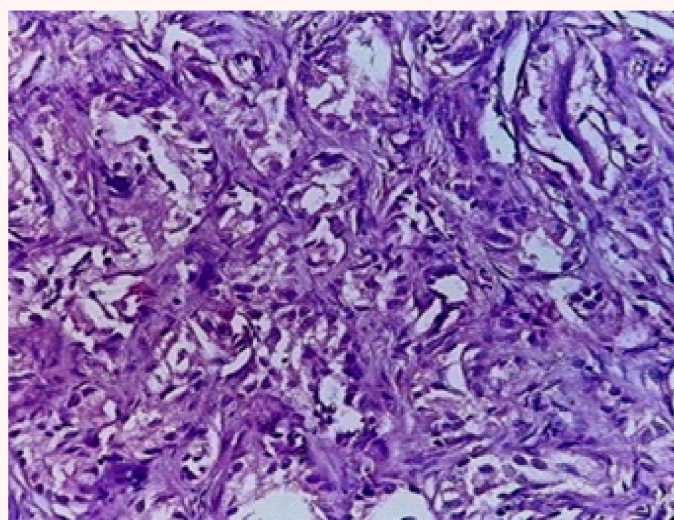


Figure 4 Features of adenocarcinoma of prostate (H & E: 100 X)

DISCUSSION

The objective of this study was to evaluate the serum PSA levels in 71 patients presenting with an enlarged prostate and to evaluate the efficiency of serum PSA to diagnose and differentiate benign from malignant enlargements.

Histologically, it was seen that out of total cases (N=71), most of the cases were benign, comprising of 59 (83.10%) cases followed by premalignant (HGPIN) and malignant cases comprising of 7 (9.85%) and 5 (7.04%) cases respectively (**Table 1**). Studies in India and abroad also observed predominance of benign lesions comprising of 74.52% - 94%.⁷⁻⁹

Benign lesions comprised predominantly of nodular hyperplasia of prostate (**Figure 1**) consisting of 45 cases (63.38%) which are in concordance with other studies with an incidence of 74.52% - 79% (**Table 1**). Inflammatory lesions including granulomatous prostatitis (**Figure 2**) are observed in 4.23% cases which is much higher than the published data of 1.4% - 2.82%.¹⁰

Basal cell hyperplasia comprised of 2 (2.82%) cases of nodular hyperplasia in the present study which is much lower than the published data of 8.2%.¹¹ Most common histomorphological variables observed in this study for benign lesions were papillary infoldings, cystically dilated glands, corpora amylacea and presence of basal cells (**Table 2**).

High-grade prostate intraepithelial neoplasia comprised of 7 (9.86%) cases in the present study which is quite similar to other observations.¹² In this study, features considered under nuclear atypia were nuclear stratification, nucleomegaly, irregular nuclear contour and prominent nucleoli (**Figure 3**). Similar morphology with nuclear crowding and stratification has been suggested as a very important histological feature for HGPIN diagnosis on prostate intraepithelial neoplasia.¹³ Other features like single cell layer, central necrosis and mitosis were also seen in 3 (42.86%), 2 (28.57%) and 1 (14.29%) cases respectively (**Table 3**).

Prostatic adenocarcinoma comprised of 5 (7.04%) cases.

Out of the 5 cases, 4 (5.63%) cases were acinar type adenocarcinoma (**Figure 4**) and 1 (1.41%) case was of adenocarcinoma of mixed acinar and ductal type. Published data shows variable incidence from 0.73% to 24.6% from different countries.^{7-9,14} One of the malignant cases was of a mixed acinar and ductal type, where there were papillary structures. Some authors described papillary and cribriform architecture as the two most common patterns of ductal carcinoma subtype.¹⁵

Serum PSA was assessed in all the cases (N=71) and the findings were divided into 3 categories; 0-4ng/ml, 4-10ng/ml and >10ng/ml, accordingly, age group and histological diagnosis were correlated³. Serum PSA level of 0-4 ng/ml, comprising of 67.61%, followed by >10ng/ml comprising of 16.90% and then 4-10ng/ml comprising of 15.49% cases were observed in the present study. Gleason score was assessed in all the malignant cases. Gleason score 3+3=6 was seen in 2 cases, score 3+4=7 in 1 case, 1 case seen each in acinar type (4+5=9) and mixed acinar and ductal type (3+5=8) of prostate adenocarcinoma. In our study, it was seen that score 6 was more commonly seen.

HPE & PSA correlation studies: A statistically significant positive correlation was seen between serum PSA and histological diagnosis ($r = 0.538$, $p = 0.000$), benign lesions of prostate had lower serum PSA values and premalignant & malignant lesions of prostate had higher serum PSA values. In the present study, it was seen that all the benign lesions had a serum PSA level of less than 10ng/ml; mostly comprising of 0-4ng/ml, premalignant lesions had a serum PSA level of 11-20ng/ml and all the malignant lesions had a serum PSA level of more than 20ng/ml. It was seen that in most of the benign cases including 44 cases of nodular hyperplasia of prostate, 1 case of nodular hyperplasia of the prostate with basal cell hyperplasia and 3 cases of nodular hyperplasia of the prostate with granulomatous prostatitis had a serum PSA level of less than 4ng/ml (**Table 4**).

A study on serum PSA level reveals that PSA level of 0-4ng/ml was significantly associated with benign lesions and values more than 20ng/ml was associated with malignant lesions which were similar to the findings of our study. It was seen that nodular hyperplasia of prostate associated with extensive inflammation had a serum PSA level more than 4ng/ml. Few studies had also found that inflammatory lesions of prostate correlate with low serum PSA levels.¹⁶ Some researchers claim a good rate of detectable prostate cancer with serum PSA levels of 2.6- 4.0 ng/ml.¹⁷⁻¹⁹ Therefore, these findings were discordant with our study. A strong correlation between age and histological diagnosis ($r = 0.242^*$, $p = 0.042$) was observed in the present study with benign and premalignant lesions are seen at an earlier age compared to malignant lesions. Similar findings were observed in a study comprising a large number of cases. The present study did not find any correlation between Gleason score and a serum PSA level ($r = -.258$, $p = 0.676$), contrary to the claim by some studies.^{20,21}

CONCLUSION

In this study, an attempt was made to analyze the histomorphological features of prostate biopsies and to further correlate them with serum PSA levels. The study showed that there is a statistically positive correlation between histological diagnosis and serum PSA. In all cases of malignancy, Gleason score was correlated with serum PSA values. However, the present study did not reveal any correlation between the two variables contrary to some published reports.

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Contribution of authors: (1) The article is original with the author(s) and does not infringe any copyright or violate any other right of any third party. (2) The article has not been published (whole or in part) elsewhere and is not being considered for publication elsewhere in any form, except as provided herein. (3) All author(s) have contributed sufficiently in the article to take public responsibility for it and (4) All author(s) have reviewed the final version of the above manuscript and approved it for publication.

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ORIGINAL RESEARCH PAPER

A study on the incidence and severity of hand-foot syndrome in cancer patients treated with capecitabine

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ABSTRACT

Introduction: Hand-Foot Syndrome is a localised dermatologic reaction and is one of the most common adverse effects of capecitabine containing chemotherapy in cancer patients. Although it is not life-threatening toxicity, it can be quite serious, leading to a delay in or discontinuation of anticancer therapy. **Objectives:** To estimate the incidence of Hand-Foot Syndrome receiving treatment with capecitabine containing chemotherapy at State Cancer Institute and to determine the severity of Hand-Foot Syndrome. **Materials and methods:** The study was a hospital-based retrospective study conducted at a State Cancer Institute in Assam, for a period of six months from August 2019 to January 2020. A total of fifty-one cancer patients were included, out of which thirty-three had Hand-Foot Syndrome. **Results:** Overall incidence of Hand-Foot Syndrome was 64.7% cases, 39.4% of cases in males and 60.6% cases in females. As per NCI-CTCAE grading, 60.6% of cases had grade 1 HFS, 36.4% of cases had grade 2 and 3% of cases had grade 3 HFS. The first episode of HFS occurred in 12.1% cases after cycle 1, 60.6% cases after cycle 2 and 27.3% cases after cycle 3. **Conclusion:** The incidence of HFS is common in patients treated with capecitabine and is usually starts within the first two cycles of therapy. It has a significant influence on patients quality of life and abilities.

Keywords: NCI-CTCAE; monotherapy; combination therapy.

INTRODUCTION

Hand-foot syndrome(HFS), which is also known as palmoplantar erythrodysesthesia is a localized dermatologic reaction associated with the initiation of therapy with certain

chemotherapeutic agents and is the most frequently reported side effect of oral capecitabine.¹ Hand-foot syndrome (HFS) has been previously reported as a side effect in 45-56% of patients treated with capecitabine.²

Although the exact pathogenesis of HFS is not clear, it may be due to damaged deep capillaries in the soles of the feet and palms of the hands, leading to a COX inflammatory-type reaction, or related to enzymes involved in the metabolism of capecitabine, namely, thymidine phosphorylase and dihydro pyrimidine dehydrogenase.³

The pathological changes which occurred include the vacuolar degeneration of the basal keratinocytes, dermal perivascular lymphocytic infiltration, apoptotic keratinocytes and dermal edema.⁴ The clinical features of HFS are characterized by a prodrome of dysesthesia, painful oedema and erythema of the palms, digits, and soles which may evolve into blisters and erosions.¹ Although not a life-threatening toxicity, it can be quite serious, leading to a delay in or discontinuation of anticancer therapy and affecting normal daily activities and the quality of life. If not promptly managed, HFS can progress to an extremely painful and

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debilitating condition, causing significant discomfort and impairment of function, potentially leading to worsened quality of life in patients receiving capecitabine.⁵

However, treatment interruption and or dose reduction usually leads to rapid reversal of the signs and symptoms of HFS along with supportive treatments can help alleviate it.⁶ This study aims to estimate the incidence of Hand-Foot Syndrome among cancer patients receiving treatment with capecitabine containing chemotherapy at state cancer institute and to determine the severity of Hand-Foot Syndrome.

METHODS AND MATERIALS

The study was a hospital-based retrospective study conducted at State Cancer Institute (SCI) in Assam, who attended the Department of Medical Oncology for a period of six months from August 2019 to January 2020. A total of Fifty-one cancer patients were included, who attended for the capecitabine therapy. Out of these fifty-one patients, thirty-three had Hand-foot syndrome. The data were collected from the Medical Records Department and patient's records were taken according to criteria as below: **Inclusion criteria:** 1) Above 18 years age group; 2) Patients who were on treatment with capecitabine containing chemotherapy. **Exclusion criteria:** 1) Less than 18 years age group; 2) Pregnancy; 3) Lactating mother. We retrieved the data regarding patient's characteristics (age, sex, performance status, the severity of HFS, first episode of HFS from which cycle of chemotherapy, dose adjustment requirement, capecitabine therapy as either monotherapy or combination therapy and chemotherapy settings as either adjuvant or palliative) by reviewing the patient's file from Medical Records Department.

Patients who were on capecitabine were assessed clinically/physically in every cycle receiving capecitabine chemotherapy.

As per NCI CTCAE grading, the severity of Hand-Foot Syndrome was graded who were on capecitabine therapy as shown in **Table 1**.

Table 1 National cancer institute common terminology criteria for adverse events¹

Grade 1	Minimal skin changes (erythema, oedema or hyperkeratosis) without pain.
Grade 2	Skin changes (peeling, blisters, bleeding, oedema or hyperkeratosis) with pain, limiting instrumental activities of daily living.
Grade 3	Severe skin changes (peeling, blisters, bleeding, oedema or hyperkeratosis) with pain, limiting self-care activities of daily living.

Performance status is assessed using Eastern Cooperative Oncology Group (ECOG) performance status grading as shown in **Table 2**.

Table 2 ECOG Performance Status⁷

Grade 0	Fully active, able to carry on all pre-disease performance without restriction
Grade 1	Restricted in physically strenuous activity, but ambulatory and able to carry out work of light and sedentary nature
Grade 2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of working hours
Grade 3	Capable of only limited self-care, confined to bed or chair more than 50% of working hours
Grade 4	Completely disabled. Cannot carry on any self-care. Confined to a bed or chair
Grade 5	Dead

RESULTS

In this study, out of 33 cases of HFS, 13 were males (39.4% cases) and 20 were females (60.6%) with male-female ratio were 1:1.5. As per NCI CTCAE grading, 60.6% of cases had grade 1 HFS, 36.4% of cases had grade 2HFS and 3% of cases had grade 3 HFS. The first episode of HFS occurred in 12.10% cases after cycle 1, 60.60% cases after cycle 2, 27.30% cases after cycle 3 and none occurred after cycle 4. Dose adjustment was done among 33 cases of HFS, of which 12 cases had received 75% of the total dose, 5 cases had received 50% of total dose and other 2 cases were discontinued. Capecitabine induced HFS to include primary diseases like CA stomach, CA colon, CA breast, CA rectum etc. About 19 cases (57.60%) received capecitabine as monotherapy and 14 cases (42.4%) as combination therapy. Some 12 cases (36.4%) was on adjuvant setting and 21 cases (63.6%) were on the palliative setting.

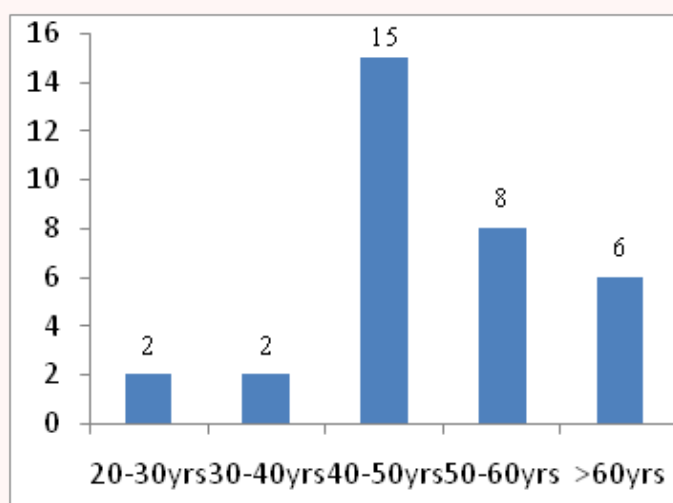
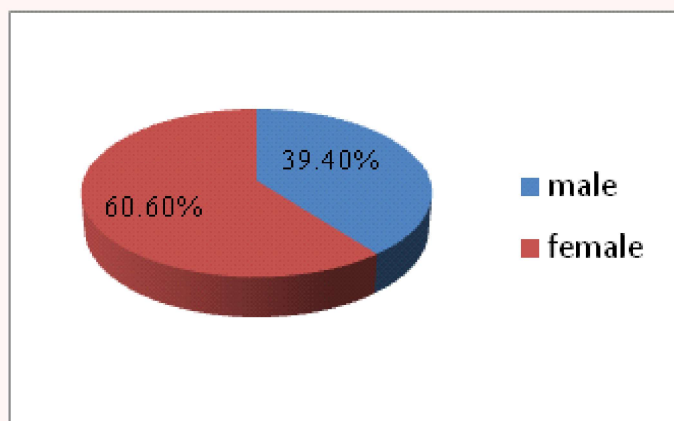
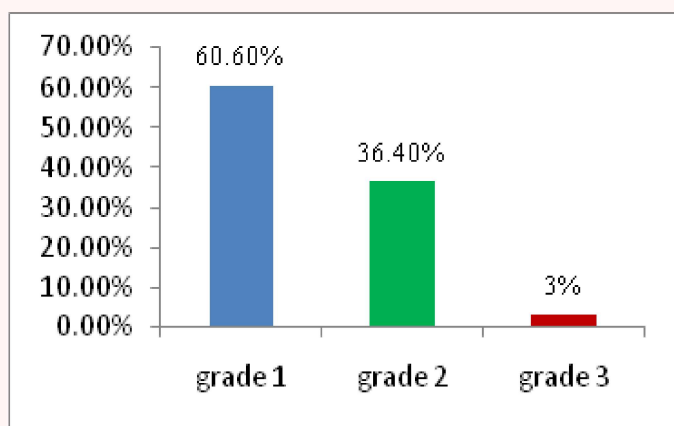


Figure 1 Age distribution

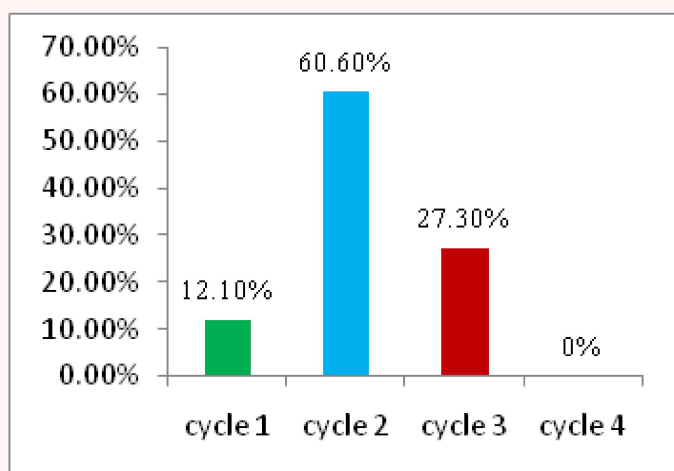
Among 33 HFS patients, 2 cases were in 20-30 yrs age group, 2 cases were in 30-40 yrs age group, 15 cases were in 40-50 yrs age group, 8 cases were in 50-60 yrs age group and 6 cases were in >60 yrs age group.

**Figure 2** Gender distribution

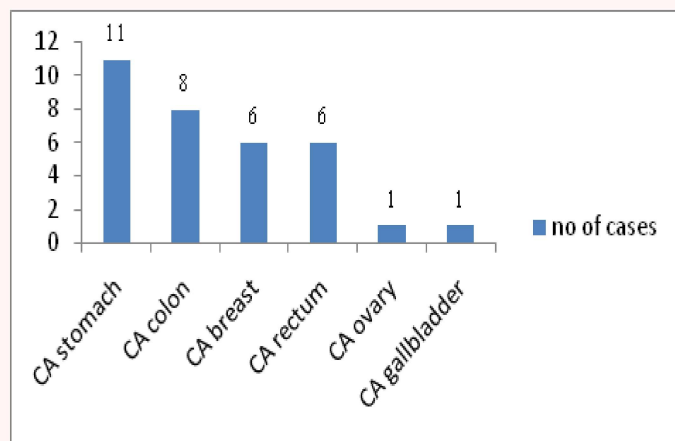
Out of 33 HFS patients, 13 cases were males (39.4% cases) and 20 cases were females (60.6%) with male-female ratio was 1:1.5.

**Figure 3** Severity of HFS

As per NCI CTCAE grading, 60.60% of cases had grade 1 HFS, 36.40% of cases had grade 2 HFS and 3% of cases had grade 3 HFS.

**Figure 4** First episode of HFS

The first episode of HFS occurred in 12.10% cases after cycle 1, 60.60% cases after cycle 2, 27.30% cases after cycle 3 and none occurred after cycle 4.

**Figure 5** Primary diseases

Patients those who were on Capecitabine induced HFS includes primary diseases like CA stomach (11 cases), CA colon (8 cases), CA breast (6 cases), CA rectum (6 cases), CA Ovary (1 case) and CA Gall bladder (1 case).

DISCUSSION

In this study, the overall incidence of HFS was found to be 64.7%, with a slight predominance among females with male-female ratio was 1:1.5 (13 males and 20 females).

In this study, 60.6% of cases experienced grade 1 HFS. A study done by Matsuoka Hiroshi et al had 66.7% cases of grade 1 HFS, 10% cases of grade 2 and none had grade 3 HFS.⁸ The Study of Azuma Yuichiro et al showed 37.8% cases of grade 1 HFS, 31.6% cases of grade 2 and 3.1% cases of grade 3.⁹ A Study done by Yap Yoon Sim et al found 28.6% of grade 1 HFS, 31.42% of grade 2 and 2.9% of grade 3 HFS.⁶ Son Hyun Sook et al study showed that 50.7% had grade 1, 33.8% had grade 2 and 15.5% had grade 3.¹⁰

Among the 33 patients who had HFS, 20 patients (60.6%) had their first episode after cycle 2. The Study done by Son Hyun Sook et al showed that 26.1% had the first episode of HFS after cycle 1 and 73.9% had after cycle 2.⁹

In this study, 12 cases (36.4%) of HFS was on adjuvant setting and 21 cases (63.6%) of HFS was on the palliative setting. A Study done by Yap Yoon Sim et al found that those who had HFS had 21% cases were on adjuvant and 79% cases were on palliative.⁶

In the present study, about 19 (57.60%) cases, received capecitabine as monotherapy and 14 (42.4%) cases as combination therapy. A study done by Muller Volkmar et al showed that those who had HFS received capecitabine as monotherapy in 38.8% cases and 61.2% cases received as combination therapy.¹¹

CONCLUSION

The incidence of HFS is common in patients treated with capecitabine and is usually starts within the first two cycles of therapy. Although the incidence of a severe grade of HFS is low, it can have a significant influence on patient's quality of life and abilities. Prevention, early recognition, and

implementation of various management strategies for HFS are important in optimizing patient's quality of life and minimizing unfavourable outcomes. The study comprises of relatively a small sample size for a short period. Hence, a larger prospective study with a large sample size for long duration is required to arrive at a definite conclusion. Whether the results of the present study can be reproduced in other multicentre studies has yet to be determined. Further studies are therefore necessary.

Limitations: Varying doses of capecitabine used in this study and relatively small sample size and short duration of the study.

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Author Contributions: Conception/design: Dr Niharika Kutum, Dr Neelakshi Mahanta, Dr Naba K Kalita; Provision of study material or patients: Dr Niharika Kutum, Dr Neelakshi Mahanta, Dr Naba K Kalita, Dr Hitesh Deka, Dr Pooja Lokkur, Dr Alfarid S Ali; Collection and/or assembly of data: Dr Niharika Kutum, Dr Alfarid S Ali, Dr Hitesh Deka, Dr Pooja Lookur; Data analysis and interpretation: Dr Niharika Kutum, Dr Naba K. Kalita, Dr Neelakshi Mahanta; Manuscript writing: Dr Niharika Kutum Final approval of Manuscript by all the authors.

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ORIGINAL RESEARCH PAPER

Knowledge and attitude regarding reproductive health among women

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ABSTRACT

Introduction: Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, as so, reproductive health addresses the reproductive processes, functions and system of all stages of life. Unmet needs for reproductive health deprive women of the right to make 'crucial choices about their bodies and futures' affecting family welfare. **Objectives:** The study was conducted to assess the knowledge and attitude of women regarding reproductive health in selected offices of Guwahati, Assam, to find out the correlation between knowledge and attitude regarding reproductive health among women and to find the association of knowledge and attitude with selected demographic variables. **Materials and methods:** A quantitative approach and survey research design were used in this study. The technique adopted was self-reporting technique. Using a non-probability convenient sampling technique, sample size of 100 working women from three selected offices in Guwahati were taken for the study. A structured questionnaire was used to assess knowledge and 3-point Likert scale to assess attitude. **Results:** It was found that out of 100, 51% moderately adequate, 28% inadequate and the rest 21% had adequate knowledge and 52% desirable attitude and 48% moderately desirable attitude. There was a moderately positive correlation between knowledge and attitude. Knowledge of the women regarding reproductive health had a significant association with their educational status at 0.05 level of significance. Attitude had a significant association with their education status. **Conclusion:** The study reveals that women have moderately adequate knowledge and desirable attitude and also found that there is a positive

correlation between knowledge and attitude regarding reproductive health.

Keywords: Knowledge; attitude; reproductive tract infection.

INTRODUCTION

Reproductive health is a crucial part of general health and a central feature of human development.¹ Reproductive health relates to the maintenance of one's reproductive health system and fertility. Its components include birth control, prevention and management of sexually transmitted infections, safe abortion service and prevention and management of infertility. The main focus of the study on reproductive health has been on the two aspects, viz. birth control and prevention and management of sexually transmitted infections.

Most individuals and couples want to plan the timing and spacing of their childbearing and to avoid unintended pregnancies, for a range of social and economic reasons. Besides, unintended pregnancy has a public health impact: Births resulting from unintended or closely spaced pregnancies are associated with adverse maternal and child health outcomes, such as delayed prenatal care, premature birth and negative physical and mental health effects for

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children.² Effective contraceptive counselling not only requires accurate knowledge of current contraceptive choices but also a non-judgmental approach woman should be encouraged to talk about intimate family and individual issues. The goal of contraceptive counselling is to ensure that women receive appropriate instruction to take charge of their own reproductive choice. Reproductive tract infections include a variety of bacterial, viral, protozoal, fungal and ectoparasites infections of the lower and upper reproductive tract of both sexes. Reproductive Tract Infection (RTI) pose a threat to women's lives and wellbeing throughout the world. In India, the prevalence of reproductive tract infection is very high due to the silent epidemic. The low status of women in many parts of India makes women suffer in silence or even feel too ashamed to seek treatment. Vaginal discharge is amongst the first 25% reasons to consult doctor, 40% gynaecological OPD attendance is because of RTIS and 16% of gynaecological admissions are due to pelvic inflammatory disease.³ The population prevalence of STIs such as syphilis, gonorrhoea, and chlamydia has a range of 0-3.9% in India but the STI burden is much higher among subpopulations practising high-risk behaviour.⁴ It is currently estimated that India has 2-3 million individuals infected with HIV, and the primary mode of HIV transmission has been via heterosexual contact. HIV transmission is strongly associated with repeated sexually transmitted infections (STIs) and sexual behaviour. HIV and STIs are linked in that both are transmitted by unprotected sexual behaviour.⁵ In the view of the above studies & the magnitude of the problems related to elements of reproductive health that are the failure of family planning practices and RTI/STD. An analysis of knowledge and attitude regarding reproductive health among women reproductive age group is required. Objectives of this study are (i) to assess the knowledge regarding reproductive health

among women in selected offices of Guwahati. (ii) to assess the attitude regarding reproductive health among women in selected offices of Guwahati. (iii) to correlate the knowledge and attitude regarding reproductive health among women in selected offices of Guwahati. (iv) to find out the association of knowledge and attitude regarding reproductive health among women with selected demographic variables viz. age, education, income, marital status, use of contraceptives measures.

MATERIALS AND METHODS

A quantitative approach and survey research design were used in this study. The technique adopted was self-reporting technique. Using non-probability convenient sampling technique, 100 women from three settings Rashtriya Madhyamik Siksha Abhiyan Kahilipara, Agriculture office Khanapara and The North Eastern Development Finance Corporation Ltd, Guwahati were taken for the study. Exclusion criteria were women who cannot read and write English. A structured questionnaire was used to assess knowledge and 3-point Likert scale to assess attitude. The validity of the tool was established in consultation with a guide and from experts in obstetric and gynaecological. The reliability of the tool was 0.8 by Split Half method which was considered to be reliable and adequate. The data was collected from 4th July–30th July 2016.

RESULTS

The **Table 1** depicts that out of 100 samples, majority of 51 (51%) respondents had moderately adequate knowledge, 28 (28%) respondents had inadequate knowledge and 21 (21%) respondents had adequate knowledge. The mean knowledge was 12.7 with a standard deviation of 5.4 and ranges from 2-25.

Table 1 Frequency and percentage distribution of knowledge level regarding reproductive health among women (n=100)

Knowledge	Frequency	Percentage	Mean	SD	Range of scores	Total score
Inadequate (<33%) (<9 marks)	28	28%	12.7	5.4	2 – 25	26
Moderately adequate (33 – 66%) (9 – 17 marks)	51	51%				
Adequate (>66%) (>17 marks)	21%					

Table 2 depicts that out of 100 samples, majority 52 (52%) responded had desirable attitude whereas 48 (48%) respondents moderately desirable attitude. The mean attitude was 29.95 with a standard deviation of 9.33 and ranges from 16-45.

Table 2 Frequency and percentage distribution level of attitude score of the respondents

Attitude	Frequency	Percentage	Mean	Sd	Range of scores	Total score
Undesirable (<33%) (<15 marks)	0	0%	29.95	9.33	16 - 45	45
Moderately desirable (33-66%) (15 - 30 marks)	48	48%				
Desirable (>66%) (>30 marks)	52	52%				

The data represented in **Table 3** shows the correlation between knowledge and attitude of women regarding reproductive health. The correlation was statistically calculated by using Karl Pearson correlation coefficient. The calculated r-value was found to be $r = 0.3$.

Therefore, there was a moderately positive correlation between knowledge and attitude regarding reproductive health. Thus, with an increase in knowledge, there is a gradual increase in attitude.

Table 3 Correlation between knowledge and attitude scores of the respondents

Variables	Mean	SD	Correlation coefficient
Knowledge	12.7	5.4	0.3
Attitude	29.95	9.33	

Table 4 Association of knowledge with age, education, marital status and use of contraceptives (n = 100)

Variables	IA	MA	A	Total	Cal. value	Tab. value	df	Remark
Age group								
18 – 34 years	10	18	7	35	0.03	5.99	2	NS
35 – 50 years	18	33	14	65				
	28	51	21	100				
Educational status								
Under graduate	12	7	11	30	13.64	5.99	2	Sign
Graduate and above	16	44	10	70				
	28	51	21	100				
Marital status								
Unmarried	7	11	7	25	1.11	5.99	2	NS
Married	21	40	14	75				
	28	51	21	100				
Use of contraceptives								
No	22	46	16	84	3.33	5.99	2	NS
Yes	6	5	5	16				
	28	51	21	100				

Note: For calculation purpose, clubbing of the scores were done and chi-square formula is applied.

$$\chi^2 = P \text{ at } 0.05$$

IA- Inadequate, MA- Moderately adequate, NS- Non-significant, df – Degree of freedom.

Table 4 shows that the obtained value (0.03) was less than the tabulated value (5.99) at 0.05 level of significance with df 2. Hence, there is no association between knowledge and age group of respondents.

The table shows that the obtained value (13.64) was more than the tabulated value (5.99) at 0.05 level of significance

with df 2. Hence, there is an association between knowledge and educational status of respondents.

The table shows that the obtained value (1.11) was less than the tabulated value (5.99) at 0.05 level of significance with df 2. Hence, there is no association between knowledge and marital status of respondents.

The table shows that the obtained value (3.33) was less than the tabulated value (5.99) at 0.05 level of significance with df 2. Hence, there is no association between knowledge and use of contraceptives.

n = 100

Table 5 Association of attitude with age, education, marital status and use of contraceptives

Variables	MD	D	Total	Cal. value	Tab. value	Df	Remark
Age group							
18 - 34	19	16	35	0.69	3.84	2	NS
35 - 42	19	20	39				
43 - 50	10	16	26				
	48	52	100				
Educational status							
Under graduate	22	8	30	11	3.84	1	Sign
Graduate and above	26	44	70				
	48	52	100				
Marital status							
Unmarried	12	13	25	0	3.84	1	NS
Married	36	39	75				
	48	52	100				
Use of contraceptives							
No	41	43	84	0.12	3.84	1	NS
Yes	7	9	16				
	48	52	100				

NOTE: For calculation purpose, clubbing of the scores were done and chi-square formula is applied.

$$\chi^2 = P \text{ at } 0.05$$

MA- Moderately adequate, D- Desirable, NS- Non-significant, Sign- Significant, df – Degree of freedom.

Table 5 shows that the obtained value (0.69) was less than the tabulated value (3.84) at 0.05 level of significance with df 1. Hence, there is no association between attitude and age group of respondents. The table shows that the obtained value (11) was more than the tabulated value (3.84) at 0.05 level of significance with df 1. Hence, there is an association between attitude and educational status of respondents. The table shows that the obtained value (0) was less than the tabulated value (3.84) at 0.05 level of significance with df 1. Hence, there is no association between attitude and marital status of

respondents. The table shows that the obtained value (0.12) was less than the tabulated value (3.84) at 0.05 level of significance with df 1. Hence, there is no association between attitude and use of contraceptives.

DISCUSSION

In this study, out of 100, 51 (51%) moderately adequate, 28 (28%) inadequate and the rest 21 (21%) had adequate knowledge and 52 (52%) desirable attitude and 48 (48%) moderately desirable attitude. The mean of knowledge and attitude was (12.7) and (29.95) respectively. There was a moderately positive correlation between knowledge and attitude. Knowledge of the women regarding reproductive health had a significant association with their educational status

at 0.05 level of significance. Attitude had a significant association with their education status at 0.05 level of significance. The study findings support the study conducted to assess knowledge, attitude, and practice studies on adolescents and youth concerning their reproductive health in India. The objective of the study is to develop a replicable model for the provision of sexual and reproductive health services to college-based youth in Thane district. A self-administered semi-structured questionnaire was used for the survey, which included 800 Male and 700 Female in the age group 15-24 years. The study findings showed students lacked scientific information and misconceptions are widespread on various reproductive health issues.⁶ Kibert M (2009), conducted a study to assess the reproductive health knowledge, attitude and practice among high school students in Bihar Dar, Ethiopia. A self-administered questionnaire was used and focus group discussions. The study findings showed the students had high-level knowledge of contraceptives and where to obtain contraceptive services; however, level of use was low and that young person engages in sexual relationships at an early age without protection or with unsafe non-conventional methods. The educational level of the respondents was the only demographic variable that had a significant association with sexual experience ($p < 0.05$). The study concluded that family planning information and services and family life education programme based on the needs and experience of these young people as a potential solution to alleviate their reproductive health problems.⁷ Jyoti Vinod (2008), conducted a study to assess the effect of planned teaching programme on knowledge, attitude and practice of adolescents concerning the reproductive health in selected shelter homes in Mumbai, among a population of 60 adolescents in that 30 boys and 30 girls who were selected by convenient sampling technique and data were collected by self-reporting technique. The study findings showed that pre-test knowledge score is 63% and the post-test score is 91% concerning knowledge changed in the adolescence was markedly increase in boys and girls from 23% and 19% to 70% and 83% respectively. The study concluded that teaching programme on reproductive health is effective.⁸ Savitri R (2008), conducted a study to determine the effectiveness of health education in improving knowledge regarding reproductive health among adolescent girls of 16-19 years in Udupi district Karnataka. The sample size was 791 girls. Their awareness assessed immediately following the intervention. Chi-square test used for analysis. The study finding showed significant improvement in knowledge after intervention from 14.4% - 68% ($p < 0.01$) was observed regarding contraception. The study concluded that education intervention program can bring about desirable change in knowledge among girls regarding reproductive health.⁹ Anant, Barwal, Singh A (1994), conducted a study to measure the effectiveness of a reproductive health education package in improving the knowledge of adolescent girls aged 15-19 years in Chandigarh. Using a 70-item structured questionnaire the knowledge of 95 adolescents from conventional, 84 from the peer, and 94

from control school were assessed before and one month after the last session. The study finding showed that reproductive health knowledge scores improved significantly after intervention in conventional education (27.28) and peer education group (20.77) in comparison to the controls (3.64). The study concluded that peer education and conventional education strategies were effective in improving the reproductive health knowledge of adolescent girls but peer strategy was less time consuming.¹⁰

CONCLUSION

The study reveals that women have moderately adequate knowledge and desirable attitude regarding reproductive health. It is also found that there is a positive correlation between knowledge and attitude regarding reproductive health. The investigator has drawn the following implications from the study which is a necessary concern to the field of nursing service, nursing education, nursing administration and nursing research.

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Contribution of authors: We declare that this work was done by the authors named in this article and all liabilities about claims relating to the content of this article will be borne by the authors.

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ORIGINAL RESEARCH PAPER

Microbiological profile of ear discharge of chronic suppurative otitis media (safe variety) patients

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ABSTRACT

Introduction: Chronic suppurative otitis media is a notorious infection and a major health problem in developing countries causing serious local damage and threatening complications. Early and effective treatment based on the knowledge of causative micro-organisms and their antimicrobial sensitivity ensures prompt clinical recovery and possible complications can thus be avoided. **Aim:** This study was undertaken to identify the microbiological isolates of ear discharge in CSOM cases and their sensitivity to antibiotics. **Materials and methods:** A prospective study, a total of 50 patients having ear discharge who attended ENT OPD from Feb 2019 to July 2019 for a period of 6 months were studied. Aural swabs were sent to microbiology lab for gram staining and culture sensitivity. **Results:** Out of 50 samples, 32 were culture positive where *Pseudomonas aeruginosa* (37.5%) was the most common pathogen followed by *Staphylococcus aureus* (28.12%). Most of the cultured organisms were sensitive to drug Ciprofloxacin. **Conclusion:** The outcome of our study enabled us to set an empirical medical treatment for an early resolution of ear discharge and inflammation in our patients with CSOM as we could understand the aetiological pathogens and their susceptibility pattern. Effective medical treatment in obtaining a discharge free ear prior to surgical treatment led us to improve the surgical outcome in our patients with CSOM.

Keywords: Tubo-tympanic; *Pseudomonas aeruginosa*; culture and sensitivity.

INTRODUCTION

Chronic Suppurative otitis media (CSOM) denotes chronic inflammation within the mucosa of middle ear and mastoid

leading to production of ear discharge via tympanic membrane perforation.¹ CSOM results from long term Eustachian tube dysfunction with poorly aerated middle ear space, multiple bouts of acute otitis media and persistent middle ear infection.² Risk factors include mechanical obstruction of Eustachian tube due to adenoid hypertrophy, sinusitis, immunodeficiency and environmental factors such as lack of breast feeding in infancy, passive exposure to smoking and low socio economic status.³ Major cause of ear infection are bacterial isolates predominantly aerobic gram-negative bacteria such as *Pseudomonas*, *E. coli*, *Proteus*, *klebsiella* and gram-positive bacteria *Staphylococcus* spp. Anaerobic bacteria include *bacteroid* spp. Frequent upper respiratory tract infections and poor socio-economic status condition, overcrowded housing, poor hygiene, and poor nutrition may be related to development of CSOM.⁴

CSOM has profound impact on society by causing deafness in more than one third of the population in developing countries, and is believed to be responsible for more than two thirds of deafness in children thereby causing intellectual and educational problems. If untreated CSOM may lead to complications including septicemia, meningitis, brain abscess and facial palsy. Therefore, the microbial culture and sensitivity

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will help in appropriate management of otitis media and its complications and thus preventing the emergence of resistant bacterial strains.⁵

The treatment of CSOM is controversial and subject to change particularly in the developing countries, the prevalence and antibiogram of these organisms has been reported to vary with time and geographical area as well as continent to continent, probably due to indiscriminate use of antibiotics. Hence, the periodic update of prevalence and antibiogram of the etiological agents for CSOM would be helpful in therapy and management of patients.⁶

MATERIALS AND METHODS

Present study was carried out in 50 patients attending the Outpatient/in-patients Department of Otorhinolaryngology, between Feb 2019 to July 2019 with clinical evidence of CSOM. A baseline data of cases were recorded including history, general examination, systemic examination, Otorhinolaryngological examination investigations and treatment received in the past.

From each patient of active CSOM, two swabs of the ear discharge are collected under aseptic precautions without surface contamination and are transported to Microbiology department. Only those cases were selected who had not taken any treatment either systemic or local in the form of ear drops for the last seven days. One swab was utilized for Gram's staining and the other was inoculated on Nutrient agar, Blood agar and MacConkey agar for bacterial culture. After overnight incubation at 37°C the culture plates were observed for growth. Single colony was stained by Gram's Method from each culture plate. Hanging drop was done if Gram negative bacilli were seen. The cultured bacteria are subjected to various biochemical tests depending on the organism like catalase test, oxidase test, urea hydrolysis test, phenol red test etc. The organism isolated was tested for antibiotic sensitivity on Mueller-Hinton agar by Kirby-Bauer

Table 1 List of organisms isolated

Name of bacteria	No. of isolates	Percentage
GRAM NEGATIVE BACTERIA	21	65.62
<i>Pseudomonas aeruginosa</i>	12	37.5
<i>E. coli</i>	4	12.5
<i>Klebsiella</i>	3	9.37
<i>Proteus</i>	2	6.25
GRAM POSITIVE BACTERIA	11	34.38
<i>Staphylococcus aureus</i>	9	28.13
<i>Staphylococcus saprophyticus</i>	2	6.25

disc diffusion method according to National Committee for Clinical Laboratory Standards (NCCLS) criteria.

RESULTS

In our study out of 50 patients 29 (58%) were males and 21 (42%) were females with male and female ratio 1.38:1. And age range of 10-60 years.

Out of 50 samples collected from patients suffering from tubotympanic CSOM in our study, 32 (64%) samples were culture positive and 18 (36%) were culture negative.

Among the 32 bacterial isolates, *Pseudomonas aeruginosa* was the most common bacterium cultured in 12 (37.5%) samples, followed by *Staphylococcus aureus* in 9 (28.12%), *E. coli* 4 (12.5%), *Klebsiella* 3 (9.37%), *Proteus* 2 (6.25%) and *Staphylococcus saprophyticus* 2 (6.25%) as indicated in **Table 1**.

Among the 12 isolates of *Pseudomonas aeruginosa*, it showed highest sensitivity to Imipenem, i.e. 11 out of 12 isolates were sensitive (92%) followed by Ciprofloxacin, 10 out of 12 (83%), Ceftazidime 10 out of 12 (83%), Levofloxacin 8 out of 12 (67%) as shown in **Table 2**.

Table 2 Antibiotic susceptibility pattern in *Pseudomonas aeruginosa*

Antibiotic	No. of isolates sensitive/out of	Percentage
Imipenem	11/12	92
Ciprofloxacin	10/12	83
Ceftazidime	10/12	83
Levofloxacin	8/12	67

Among the 9 isolates of *Staphylococcus aureus*, it showed highest sensitivity to Ciprofloxacin, i.e. 8 out of 9 (89%) followed by Gentamicin 6 out of 9 (67%), Ofloxacin 6 out of 9 (67%), Amoxycillin 5 out of 9 (56%), Linezolid 5 out of 9 (56%) as shown in **Table 3**.

Table 3 Antibiotic susceptibility pattern in *Staphylococcus aureus*

Antibiotic	No. of isolates sensitive/out of	Percentage
Ciprofloxacin	8/9	89
Gentamicin	6/9	67
Ofloxacin	6/9	67
Amoxycillin	5/9	56
Linezolid	5/9	56

Gram negative bacteria other than *Pseudomonas aeruginosa* were mostly sensitive to Ciprofloxacin, i.e. 8 out of 9 (89%), followed by Gentamicin 7 out of 9 (78%), Amoxycillin+Clavulanic acid 7 out of 9 (78%), Ceftazidime 6 out of 9 (67%), Amikacin 5 out of 9 (56%) as shown in Table 4.

Table 4 Antibiotic sensitivity pattern in gram negative bacteria other than *Pseudomonas aeruginosa*

Antibiotic	No. of isolates	Percentage
	sensitive/out of	
Ciprofloxacin	8/9	89
Gentamicin	7/9	78
Amoxiclav	7/9	78
Ceftazidime	6/9	67
Amikacin	5/9	56

DISCUSSION

Among 50 samples collected from CSOM patients, 32 samples were bacterial culture positive with a culture positivity of 64%. In studies done by Vikas Khanna et al.,⁷ VK Poorey et al.,⁸ Tanmoy Dev et al.,⁹ and SNikakhlagh et al.,¹⁰ the culture positivity was 84%, 92%, 53% and 82% respectively.

In our study all were monobacterial cultures where as in studies done by Vikas Khanna et al.,⁷ VK Poorey et al.,⁸ polymicrobial or mixed cultures were obtained in 39% and 10% respectively.

Out of 32 bacterial isolates in the present study *Pseudomonas aeruginosa* was the predominant bacterium in 12 (37.5%) followed by *Staphylococcus aureus* in 9 (28.12%) isolates. Kenna et al.,¹¹ found that *Pseudomonas* was the predominant organism (67%) in their study. In study done by Vikas Khanna et al.,⁷ the most common bacterial isolate was *Pseudomonas aeruginosa* (40.57%), followed by *Staphylococcus aureus* in 36.23% of cases. SNikakhlagh et al.,¹⁰ studied that *Staphylococcus aureus* is the common isolate in 32.4% followed by 21.69% of *Pseudomonas aeruginosa*. VKPoorey et al.,⁸ observed that *Pseudomonas pyocyaneus* was the most common organism isolated in 35.2%, followed by *Klebsiella aerogenes* in 25.4%. The observations made from different studies indicate that there can be variation in causative organism based on ethnic, geographic factors.

In the present study Ciprofloxacin drug has emerged as the most effective antibiotic useful for the patients in our study which is sensitive against more than 80% of *Pseudomonas*, *Staphylococci* and other pathogens. In studies done by Sharma K et al.,¹² and VK Poorey et al.,⁸ Amikacin was the most effective drug.

Those patients who were culture negative were successfully treated of their ear discharge by regular dry mopping of ear, a medical treatment with oral ciprofloxacin and ornidazole

combination along with topical antifungal ear drops. This observation is suggestive of a role of anaerobes and fungal pathogens in CSOM.

Out of 50 patients in our study more than 38 patients have used antibiotics during some part of their long duration of CSOM before presenting to us. Their drug history included most commonly Cefixime, Amoxicillin with Clavulanic acid and topical Ofloxacin which were not useful for them. After obtaining the culture sensitivity report they were put on oral and topical Ciprofloxacin and we have observed early response as most of the discharging ears were dry by 2 weeks of treatment.

CONCLUSION

Chronic suppurative otitis media has become public health importance in the present days in developing countries like India, mostly seen among people with poor socioeconomic status, poor hygiene, low education and studded habitat. Irregular, haphazard and indiscriminate use of antibiotics has precipitated the emergence of multi resistant bacteria. Proper counselling about hygiene and maintenance of treatment has got an important impact. Culture sensitivity is an important tool to address the problem ethically.

Contribution of authors: (1) The article is original with the author(s) and does not infringe any copyright or violate any other right of any third party. (2) The article has not been published (whole or in part) elsewhere and is not being considered for publication elsewhere in any form, except as provided herein. (3) All author(s) have contributed sufficiently in the article to take public responsibility for it and (4) All author(s) have reviewed the final version of the above manuscript and approved it for publication.

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ORIGINAL RESEARCH PAPER

Bacteriology of chronic respiratory diseases in a tertiary care hospital in Assam

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ABSTRACT

Introduction: Chronic respiratory diseases constitute a grave problem throughout the world and particularly in middle and low-income countries. The burden of these diseases leads to poor quality of life and disability of affected individuals leading to premature deaths and a great economic loss to their families and society. **Materials and Methods:** Bronchoalveolar lavage fluid samples of patients with chronic respiratory diseases undergoing bronchoscopy in a tertiary care hospital were collected under aseptic precautions after obtaining approval from the institutional ethical committee. Antibiotic sensitivity testing was performed for the bacterial isolates. **Results:** 40 out of 110 cases (36.36%) showed the growth of pathogenic bacteria. The most common bacteria isolated were *Klebsiella pneumoniae* (14.54%) and *Pseudomonas aeruginosa* (10.90%). The other bacterial isolates were *Staphylococcus aureus* (2.72%), *Enterococcus faecium* (2.72%), *Acinetobacter baumannii* (1.18%), *Enterobacter cloacae* (1.18%), *Escherichia coli* (0.90%) and *Streptococcus pneumoniae* (0.90%). Most of the strains of *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Escherichia coli*, and *Enterobacter cloacae* were sensitive to antibiotics like piperacillin-tazobactam, cefepime, and ciprofloxacin. The gram-positive isolates showed 100% sensitivity to vancomycin and linezolid. **Conclusions:** Bronchoalveolar lavage has improved sensitivity and specificity in the diagnosis of pulmonary infections.

Keywords: Bronchoalveolar lavage (BAL); antibiotic sensitivity; bacterial isolate; *Klebsiella pneumoniae*; *Staphylococcus aureus*.

INTRODUCTION

Chronic respiratory diseases constitute a grave problem

throughout the world and particularly in middle and low-income countries. They comprise chronic diseases of the airways and other structures of the lung and account for 4 million deaths annually. The burden of these diseases leads to poor quality of life and disability of affected individuals leading to premature deaths and a great economic loss to their families and society.¹ Chronic respiratory diseases are prevalent among more than 500 million patients living in developing countries or deprived populations across the world.²

Bronchoalveolar lavage (BAL) is an invasive technique, used in the diagnosis of lower respiratory tract infections, where a saline wash of the bronchial tree is done. It was first introduced in 1970.³ It has been observed by some investigators that the first aliquot represents predominantly the airway cells and secretions and is good for microbiological analysis.⁴ One million alveoli are sampled from 1ml of secretions from the bronchoalveolar lavage fluid.⁵ The main objective of the study was to determine the common aerobic bacterial pathogens in bronchoalveolar lavage fluid from patients with chronic respiratory diseases and to determine the antibiogram of the bacterial isolates.

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MATERIALS AND METHODS

The study was carried out in the Department of Microbiology, Gauhati Medical College Hospital (GMCH), Guwahati, for a period of one year from June 2017 to May 2018 with a total of 110 samples. The study was commenced with ethical approval and clearance certificate from Institutional Ethics Committee, GMCH. Informed consent was taken from the patient and clinical details were recorded in a predesigned proforma. Adult patients with chronic respiratory diseases like bronchiectasis, COPD (Chronic Obstructive Pulmonary Disease) with respiratory tract infection, non-resolving pneumonia, interstitial lung disease, any case of hemoptysis, and any growth in endobronchial tree/lung undergoing bronchoscopy were included in the study. However, patients with unstable cardiac conditions, immunocompromised patients, pregnant women, patients who do not give consent for the procedure were excluded from the study.

Bronchoscopy procedure: The site to be lavaged was determined radiographically with the help of HRCT chest and the BAL fluid was recovered in 2-3 aliquots.⁶

Processing of the sample: The sample was centrifuged at 3000 rpm for 15-20 minutes. A smear was made from the sediment of the centrifuged BAL sample and it was subjected to Gram stain according to the methods described by Duguid JP et al.⁷ The Gram-stained smear was observed to assess the quality of the sample and also to differentiate gram-positive from gram-negative bacteria. On Gram staining, the presence of >10 squamous epithelial cells/low power field in the BAL fluid in the direct smear was considered as a criterion for sample rejection. A total of 110 BAL fluid samples that met the above quality control criteria were included in the study. For aerobic culture, the sediment of the centrifuged BAL sample was inoculated onto the Blood agar, Mac Conkey agar, and chocolate agar plates. The inoculated Blood agar and Chocolate agar plates were incubated under microaerophilic conditions with 5% CO₂ at 37°C for 24-48 hours in a candle jar. The inoculated Mac Conkey agar plates were incubated under aerobic conditions at 37°C for 24-48 hours.⁸ For the isolation of *S. pneumoniae*, 5% Sheep Blood Agar with Optochin disk was used. The blood agar plates were incubated in a candle jar, in the presence of 5% CO₂ and incubated at 35-37°C for 24-48 hours. The media used for the isolation of *H. influenzae* was Chocolate agar with a streak of *S. aureus* and incubated in an environment rich in 5% CO₂ using a candle jar at 35°C for 24-72 hours.⁶

Colony count: As a loop with a volume of 10 microliters was used, the colonies were counted and multiplied by 100, and the colony-forming unit per ml was determined. A threshold of 10⁴ CFU/ml was taken as diagnostic.^{6,9,10}

Identification: Characterization and identification of organisms were done as per Collee et al¹¹ by interpretation of the colony characteristics, gram staining, motility, biochemical tests.

RESULTS

Most of the cases in the present study were between the

ages of 51 - 60 years (21.81%) followed by 21-30 years (20.9%). There were no cases below 10 years of age. The median age is 48.5 years. **Figure 1** shows the age-wise distribution of cases.

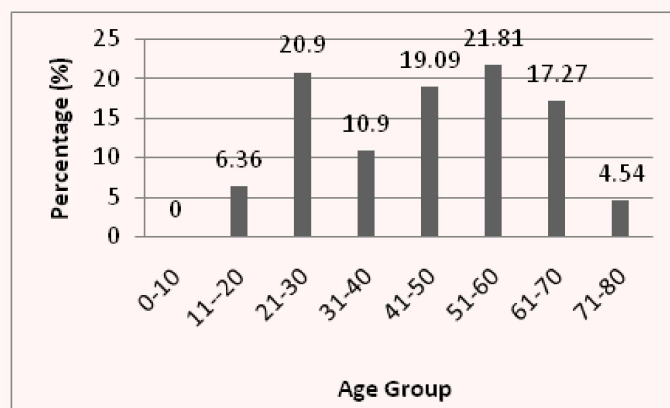


Figure 1 The age distribution of all the patients

The study shows that 71% of males and 29% of females were included in the study group. The male to female ratio was 2.5:1(M: F).

Most of the patients in this study belonged to lower (61.81%) and lower-middle (24.54%) socioeconomic status according to modified B.G. Prasad's socioeconomic status classification which applies to both urban and rural population.

Majority of the cases in this study include patients with bronchiectasis (20%), non-resolving pneumonia (19%), lung mass (17.27%), and pulmonary tuberculosis (16.36%). However, cases like carinal mass and sarcoidosis constitute a mere 0.9% of the cases. Details are shown in **Table 1**.

Table 1 The distribution of clinical diagnosis of all patients

Clinical diagnosis	No. of patients (n)	Percentage (%)
Bronchiectasis	22	20
Bronchitis	4	3.63
Interstitial lung disease	16	14.54
Carinal mass	1	0.90
Hilar mass	2	1.81
Sarcoidosis	1	0.90
Emphysema	6	5.45
Lung mass	19	17.27
Non-resolving pneumonia	21	19.09
Pulmonary tuberculosis	18	16.36
Total no of cases (N) = 110		

The study shows that 56% of the cases had a history of smoking.

Gram stain of the direct smears:

Out of 110-gram stained smears, 6.36% of the cases showed the presence of gram-positive bacteria and 30% showed gram-negative bacteria. Details are shown in **Table 2**.

Table 2 The prevalence of gram-positive and gram-negative bacteria in the direct smear

No. of smears examined.	Gram-Positive Organisms		Gram-Negative Organisms	
	No.	Percentage (%)	No.	Percentage (%)
	110	7	33	30

Table 3 The distribution of bacterial isolates associated with chronic respiratory diseases

Bacterial isolates	Number of organisms isolated	Frequency (%)
<i>Acinetobacter baumannii</i>	2	1.18
<i>Enterobacter cloacae</i>	2	1.18
<i>Enterococcus faecium</i>	3	2.72
<i>Escherichia coli</i>	1	0.90
<i>Klebsiella pneumoniae</i>	16	14.54
<i>Staphylococcus aureus</i>	3	2.72
<i>Streptococcus pneumoniae</i>	1	0.90
<i>Pseudomonas aeruginosa</i>	12	10.90
Total number of cases with bacterial isolates	40	

The above table (**Table 3**) shows that *Klebsiella pneumoniae* (14.54%) was the most commonly isolated gram-negative pathogen whereas *Staphylococcus aureus* (2.72%) and *Enterococcus faecium* (2.72%) were the most commonly isolated gram-positive pathogen.

Number of gram-positive bacteria sensitive to commonly used antibiotics and their percentage (%)

Table 4 Gram-positive bacteria (GPB) sensitive to the commonly used antibiotics

GPB	No. of Isolates	P	AMP	GEN	OF	CIP	IE	NX	CTR	AZ	E	CX	DO	TE	OP	TEI	VA	LZ
<i>S.aureus</i>	3	0(0)	2(66.6)	2(66.6)	2(66.6)	2(66.6)	2(66.6)	“,”	2(66.6)	–	0(0)	2(66.6)	3(100)	0(0)	–	–	3(100)	3(100)
<i>E.faecium</i>	3	0(0)	0(0)	–	–	3(100)	3(100)	3(100)	–	–	–	–	3(100)	3(100)	–	2(66.6)	3(100)	3(100)
<i>S.pneumoniae</i>	1	1(100)	–	–	1(100)	–	1(100)	–	–	1(100)	1(100)	–	1(100)	1(100)	1(100)	–	1(100)	1(100)

Table 4 shows the antibiotic sensitivity pattern of the gram-positive bacteria. The table shows the number of isolates sensitive to the respective antibiotic along with its percentage given in brackets. 100% sensitivity was observed in doxycycline, vancomycin, and linezolid among all the gram-positive isolates. Resistance to penicillin was observed in 100% of the isolates of *S.aureus* and *E.faecium*.

The number of gram-negative bacteria (GNB) sensitive to commonly used antibiotics and their percentage (%):

Table 5 Gram-negative bacteria (GNB) sensitive to the commonly used antibiotics

GNB	No. of isolates	AMP	DO	TE	AT	TMP/SMX	CO	E	AZ	AK	GEN	OF	CIP	LE	NX	CTR	CAZ	CTX	CPM	AMC	PIT	MRP	IPM
<i>K. pneumoniae</i>	16	7 (43.7)	9 (56.2)	-	4 (25)	-	-	-	2 (12.5)	14 (87.5)	-	-	11 (68.7)	-	-	8 (50)	-	-	9 (56.25)	2 (12.5)	12 (75)	3 (18.75)	8 (50)
<i>P. aeruginosa</i>	12	-	-	-	4 (33.3)	-	-	-	-	12 (100)	12 (100)	11 (91.6)	11 (91.6)	11 (91.6)	11 (91.6)	-	12 (100)	-	7 (58.3)	-	12 (100)	1 (8.3)	6 (50)
<i>A. baumannii</i>	2	-	1 (50)	1 (50)	-	2 (100)	2 (100)	-	-	2 (100)	2 (100)	-	2 (100)	2 (100)	-	0 (0)	0 (0)	0 (0)	0 (0)	-	-	0 (0)	0 (0)
<i>E. coli</i>	1	1 (100)	0 (0)	-	0 (0)	-	-	-	0 (0)	1 (100)	-	-	1 (100)	-	-	1 (100)	-	-	0 (0)	1 (100)	1 (100)	1 (100)	1 (100)
<i>E. cloacae</i>	2	0 (0)	1 (50)	0 (0)	2 (100)	-	-	-	1 (50)	2 (100)	-	-	2 (100)	-	-	2 (100)	-	-	2 (100)	0 (0)	2 (100)	1 (50)	2 (100)

Table 5 depicts the antibiotic sensitivity pattern of the gram-negative bacteria. Most of the isolates of *K pneumoniae* showed sensitivity to amikacin (87.5%) and ciprofloxacin (68.7%). 100% of the strains of *P aeruginosa* showed sensitivity to the aminoglycosides, ceftazidime, and piperacillin-tazobactam. *A baumannii* showed a multidrug resistance pattern with 100% of the strains being resistant to the cephalosporins, imipenem, and meropenem.

DISCUSSION

Chronic respiratory disease is a public health challenge across the world owing to the disability and economic burden associated with it. Keeping this in mind, the present study was conducted to identify the common bacterial pathogens associated with chronic respiratory diseases along with their antibiogram. The study shows that out of a total of 110 cases included in the study, most of the cases with chronic respiratory diseases were between the ages of 51 - 60 years (21.81%). Moreover, age above 65 years is a risk factor for pneumonia. The study included 78 (71%) male and 32 (29%), female patients. These findings were similar to the study by Bari SA et al.⁶ The study showed most of the cases belonged to the lower and lower-middle socioeconomic scale according to modified BG Prasad's socioeconomic status classification. Out of 110 cases, the total number of bacterial pathogens identified was found to be 40 (36.36%) which resonated with the study by Sethi S et al.¹² which showed a prevalence of

34.6%. Out of the 40 bacterial isolates, 7 (6.36%) were gram-positive cocci and 33 (30%) were gram-negative bacilli. The number of gram-positive cocci in the study resonated with the findings of Bari SA et al.⁶ in which 7 (7%) of the isolates were gram-positive. However, the prevalence of gram-negative bacilli in the present study was 30% which was comparatively lesser than the findings of the study mentioned above. The reason for this could be due to the over-enthusiastic use of empirical antibiotic therapy by the clinicians before bronchoscopy. *Klebsiella pneumoniae* (14.54%) was the most commonly isolated gram-negative bacteria. Moreover, *Klebsiella pneumoniae* is most commonly associated with elderly patients and with pneumonia in hospitalized patients. Whereas, *Staphylococcus aureus* and *Enterococcus faecium* were the most commonly isolated gram-positive bacteria. Both these findings correlated with the study by Bari SA et al.⁶ and Vivek KU et al.¹³ *Enterococcus species* are seen to be commonly associated with patients having underlying diseases. In this study, 100% of the gram-positive isolates were sensitive to doxycycline, vancomycin, and linezolid, which was in concordance with the study by Vivek KU et al.¹³ and Galate LA et al.¹⁴ Most of the gram-negative isolates in the present study showed sensitivity to aminoglycosides, fluoroquinolones, piperacillin-tazobactam, and imipenem, however, resistance was seen to aztreonam, azithromycin, amoxycylav, and meropenem. *Acinetobacter*

baumannii, being a hospital strain, was seen to be multidrug-resistant.

CONCLUSION

Chronic respiratory diseases are one of the leading causes of morbidity and mortality worldwide and especially in developing countries. The use of bronchoalveolar lavage as a diagnostic tool has proved to be a sensitive tool in diagnosing the lower respiratory tract infections associated with chronic respiratory diseases. Moreover, the abuse of antibiotics has led to the emergence of multidrug-resistant bacteria which are difficult to control. Hence it has become important to have the knowledge of the microbial flora causing lower respiratory tract infection and also to regularly monitor the antimicrobial susceptibility pattern of the microorganisms at local, regional and national levels as it would guide the physicians to prescribe the right antimicrobials and initiate the empirical therapy without leading to the emergence of multidrug-resistant strains.

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Contribution of authors: We declare that this work was done by the author(s) named in this article and all liabilities of claims relating to the content of this article will be borne by the authors. Dr Dina Raja conceived and designed the study and Dr Baishali Das was involved in collecting and analysing the data.

Author disclosure:

1. The article is original with the author(s) and does not infringe on any copyright or violate any other right of any third party.
2. The article has not been published (whole or part) elsewhere and is not being considered for publication elsewhere in any form, except as provided herein.
3. All author(s) have contributed sufficiently to the article to take public responsibility for it.
4. All author(s) have reviewed the final version of the above manuscript and approved it for publication.

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ORIGINAL RESEARCH PAPER

Effect of the video-assisted planned programme on breast self-examination among married women

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ABSTRACT

Introduction: Early detection of breast cancer plays an important role in decreasing its morbidity and mortality. This paper aims to assess the level of knowledge on breast self-examination (BSE), the effect of VAPTP (Video-assisted planned programme) and to find out the association between pre-test knowledge on BSE among married women. **Materials and methods:** An evaluative research approach and one group pre-test and post-test pre-experimental design were adopted. Multi-stage random sampling technique was used to select a sample of 116 married women who fulfilled the inclusion criteria. A self-administered structured questionnaire was used to collect the demographic variables and to assess the knowledge of BSE. In the study the independent variable was VAPTP and the dependent variable was the effect of VAPTP. **Results:** In the pre-test, 98.2% had moderate levels of knowledge on BSE and 89.66% had adequate, 10.34% had moderate levels of knowledge in post-test. The finding also shows that there is no significant association between the pre-test knowledge scores with the selected demographic variables at 0.5 levels of significance. **Conclusion:** It can be asserted that BSE is an effective way to improve the knowledge of married women. So, the health worker should conduct screening programme and health camp regarding BSE as a preventive measure of breast cancer in the society. This will be helpful to reduce stigma and attitude of society towards breast cancer and BSE.

Keywords: Breast cancer; knowledge; preventive measure.

INTRODUCTION

Breast cancer is a common cancer in women both in the developed and developing world. The incidence of breast

cancer is rising in every country of the world especially in developing countries such as India due to increasing life expectancy, increase urbanization and adoption of western lifestyles. In India, it accounts for the second most common cancer in Women.¹

The incidence of breast cancer increases with age, doubling about every 10 years until the menopause. BSE is a technique that people can try at home. The signs of the disease are the presence of lumps or thickening in the breast or armpit, discharge from the nipple, discolouration or change in the texture of the skin overlying the breast and change in the direction of the nipple.²

Reducing the incidence of advanced breast cancer by having knowledge of BSE and coupled with additional influences could promote successful ageing for elderly women.³

According to the consolidated report of the PBCRs: 2001-2004 - in India breast cancer incidence rate in Chennai 29.3%, Delhi 29.2%, Mumbai 27.5% and Bangalore 27.5% had higher age-adjusted rate than those PBCRs (population-based cancer registers) of the North-East in Aizawl 26.0% and Kamrup urban 24.3%.⁴

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BSE functions as effective preventive health behaviour. Only 19% to 40% of women practice BSE every month, and there is no strong evidence that women who practice monthly BSE perform the procedure correctly. Women need to be given the facts about breast cancer and information about early detection methods and also need to be taught BSE in such a way that they feel confident in their BSE skills.⁵

BSE is an inexpensive, risk-free method to detect cancer. When lumps are discovered at an early stage, patients have a better chance for long term survival. For women in their 20s and 30s, it is recommended that clinical breast examination must be a part of their periodic health examination. Beginning in their 20s women should be told about the benefits and limitations of BSE.⁶

BSE enables a woman or girl to detect changes in her breasts. Breast Self-Examination should be performed once every month on the women of 20 years of age and continue each month throughout a woman's lifetime. It is preferable to do Breast Self-Examination for menstruating women on the same day of each month 7-10 days after the first day of the period. For menopause and pregnant women, it is to choose the same day of every month. This method of self-examination is useful in the early detection of breast cancer.⁷

BSE is a check-up that a woman does by herself at home to look for changes or problems affecting the breast tissue. BSE is still recommended as a general approach to increase breast health awareness and thus potentially allow for early detection of any anomalies because it is free, painless and easy to practice.⁸

Cities in Assam have a surprisingly high number of breast cancers occurring in younger women, compared to rest of India. Breast cancer is more common in the younger age group and 68.8% of all women suffering from Breast cancer in Guwahati are below 50 years of age. A significant number of patients are below the age of 30 years.⁹

The investigator feels that Breast Self-Examination is an important part of female health care. It helps them to learn how their breasts normally feel so that if they find any abnormality they should know whether it is something to discuss with their health care provider. Moreover, the investigator as a community health nurse has observed that the women have less knowledge regarding BSE. Hence, the investigator has undertaken the responsibility of providing a comprehensive, non-judgemental educational package in the form of a video show to the married women on BSE to enable them to be prepared to do the self-breast examination.

MATERIALS AND METHODS

An evaluative approach with one group pre-test, the post-test pre-experimental research design was used. The study was conducted selected villages in Hajo Block Primary Health Centre, Kamrup (R), Assam. The target population for the present study was Married women of 18 to 45 years age who are residing in selected villages. Multi-stage random sampling technique was used. 10% was selected for study

from the total number of married women of 18 to 45 years. The sample size was 116.

Structured knowledge questionnaire tool was adopted. The tools consisted of three sections. **Section 1-** It contains demographic variables: Age, Religion, Education, Number of children, Occupation, Per capita family income per month and Source of information etc.

Sections 2- This part contains knowledge questionnaire on breast self-examination. Questions related to knowledge consists of 20 multiple choices items and having only one correct answer. The total score of knowledge questionnaire is 20. The total score is divided into three parts: **Inadequate**= (<5) below 25th percentile; **Moderate**= (5-15) 25th – 75th percentile and **Adequate**= (>15) above 75th percentile

Section 3- The Video Assisted Planned Teaching Programme (Assamese language) was a systematic and organized compact disc prepared by the investigator using the advance technologies of the audio and visual media to provide information to the married women in the aspects of BSE.

Reliability was checked through Karl Pearson's correlation Coefficient formula with the split-half method and "r" value was 0.716.

The data was collected after getting informed consent from the participants and concerned authorities. Pre-test and VAPTP were done on the same day of data collection. With seven days, gap post-test was done to the same subject by using the same questionnaire.

RESULTS

The findings were analyzed using descriptive and inferential statistics. Majority of sample about 47(40.5%) were in the age group 26-35 years, most of the samples 98(84.5%) belongs to Hindu religion 39(33.6%) samples had middle school passed, most of the women were housewives 67.2%, maximum married women 40.5% were <Rs. 5000 per month per capita income; 36.2% women had two children, 55.2% got the information from the health personal.

In pre-test minimum score is 4.0 and the maximum score is 16.0 and out of 116 subjects 1(0.90%) have inadequate knowledge, 114(98.2%) have moderate and 1(0.90%) have adequate knowledge.

In post-test minimum score is 13.0 and the maximum score is 20.0. And out of 116 subjects, 12(10.34%) have moderate knowledge and 104(89.66%) have adequate knowledge and none of the subjects has inadequate knowledge. The mean post-test knowledge score (17.46) is higher than the mean pre-test knowledge score (10.99). The standard deviation of the pre-test is 2.25 and post-test is 1.44. The median post-test knowledge score is higher than the median pre-test knowledge score as shown in **Table 1**.

The findings of this study revealed that the mean post-test score was higher than the mean pre-test score. The calculated "t" value was greater than the table value of $p < 0.000$ as shown in **Table 2**. Hence it is concluded that there was a

Table 1 Pre-test and post-test knowledge levels of the subjects regarding breast self-examination

Knowledge level	Mini	Maxi	Median	Mean	Stand dev.	Percentage (%)		
						Inadequate <5	Moderate (5-15)	Adequate >15
Pre-test	4	16	11	10.99	2.25	0.90	98.2	0.90
Post –test	13	20	18	17.46	1.44	0.00	10.34	89.66

n:116

significant gained knowledge through the video-assisted planned teaching programme.

There was no significant association between the pre-test

knowledge scores with selected demographic variables, i.e., age, religion, occupation, education, per capita family income per month, number of children and source of information.

Table 2 Pre-test and post-test mean knowledge score of married women regarding breast self-examination

Knowledge scores	Mean	Std. Dev.	df	t	p-value
Pre-test	10.99	2.45	115	25.783	0.000*
Post-test	17.46	1.44			

*Statistically Significant, n: 116

DISCUSSION

In the present study, findings showed that 0.9% had adequate knowledge in pre-test followed by 98.2% had moderate knowledge and 0.9% had inadequate knowledge of BSE. In post-test, 89.66% had adequate knowledge and 10.34% had moderate knowledge. In pre-test mean was 10.99 and the post-test mean was 17.46. Similar findings also have been reported by Shalini et al.,¹⁰ who investigated on Awareness and impact of education on BSE among college going girls. The study identified that 72.5% of students had average knowledge of BSE in pre-test and post-test 15% of student's average knowledge on BSE. 5% of students had good knowledge of pre-test and post-test 85% of students had good knowledge on BSE. In pre-test mean was 27 and the post-test mean was 50.

The findings of the present study state that the pre-test knowledge means the score was 10.99 and the post-test mean score was 17.46, which indicate that post-test value is higher than the mean pre-test value. This shows that married women gained knowledge through the video-assisted planned teaching programme. Similar findings were observed by Molly J et al.,¹¹ they found that the mean post-test knowledge score of the women was 7.6 and the mean post-test knowledge was 24.9. Which indicate that mean post-test value is higher than the mean pre-test value. The practice of skill in women regarding BSE revealed that the pre-test means skill score 0.7, and the post-test skill score was 12.4. This indicates the effectiveness of the Video assisted teaching programmes conducted for Married women.

In this study, there was no association between the demographic variables (age, religion, education, number of

children, occupation, per capita family income per month and source of information) and pre-test knowledge scores of Married Women regarding BSE. The present study is also supported by Molly J et al.,¹¹ where they revealed that there is an association between knowledge and selected baseline variables like age, education, and income was computed by using Pearson's product-moment correlation test and found there was no significant relationship between the pre-test knowledge score of Mahila Mandal women. The present study is also supported by Salomy C,¹² who conducted a study on knowledge of early detection of breast cancer among school teachers. the study revealed that calculated chi-square values were less than the table value for all the variables like age, the number of children, a previous source of information. Table value 5.99, 3.84; P <0.05. Hence, it is inferred that there was no association between the pre-test knowledge score and the selected baseline characteristics.

CONCLUSION

The present study showed that the knowledge of BSE among married was very less. The video-assisted planned teaching programme on BSE carried out in the study. It was found to be effective in improving the knowledge of married women as evidenced by the significant difference between the pre-test and post-test knowledge score. So, the health personnel should intensify health education on knowledge of BSE and should take initiative to improve women's practice of BSE.

Limitation: The study was limited to married women of 18-45 years age group.

Recommendation: The same type of study can be conducted on a larger sample for generalization.

Ethical clearance: Taken.

Conflicts of interest: None.

Source of funding: None.

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ORIGINAL RESEARCH PAPER

Surgery in COVID-19 times: a multicenter study for generating guidelines for open and laparoscopic procedures in both urban and rural North East Indian setting

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ABSTRACT

Introduction: Performing surgery during the COVID-19 Pandemic has caused a serious headache for the surgeons and surgical team members. Already many surgeons, as well as the team members, are exposed to the virus leading to fear and panic among the surgical fraternity. Many Surgeons succumbed to this dreaded viral disease. Many elective and semi-emergency cases are being deferred causing hardship to the patients. In such a scenario generating a universal acceptable standard operative procedures (SOP) for both the rural and urban areas is a necessity. We studied the subject in varied backgrounds and generated a guideline so that surgery can continue safely in both these backgrounds in North-East India. **Materials and methods:** We studied the cases from 01.04.2020 to 16.06.2020 done in both the rural and urban setting and found that there already exist different SOPs in various settings. We collected the guidelines and approach to these hospitals and formulated one guideline, which can be universally applied to hospitals across the region in both the rural and urban settings. **Results:** We have submitted the results of various hospitals settings and found that the results are encouraging. None of the hospitals reported the spread of COVID-19 during the study period. This encouraged us to generate a numerical checklist for any hospitals doing surgeries during this pandemic. **Discussion:** We have discussed in details about the various SOPs in place and found that many of those steps are common amongst the participating hospitals. This led us to believe that it will be useful to generate a common SOP applicable to both the rural and urban background in this region. **Conclusion:** The SOP thus generated should

be able to help in performing surgeries without fear and risk of spread of the disease.

Keywords: COVID 19; Surgery; SOP; OT Safety.

INTRODUCTION

COVID 19 has become a seriously viral Pandemic. Many interesting facts are coming to the front daily. Initially thought to be spread by droplets, it is now confirmed to be spread by aerosol. The aerosol-generating procedures (AGP) are defined now.¹ The WHO is visibly confused and it is showing in its flip-flops on the disease. The behaviour of the disease is different from the presently known behaviours of the CORONA spectrum.² The autopsy findings are very alarming.³ The lungs get badly damaged in this disease. The intravascular coagulation is also baffling. Already transplantation was needed for the illness on a young adult in the USA.⁴ Several healthcare givers have become infected and many have lost their lives. The operation theatre

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environment is the most dangerous. The basic safety protocols are not possible to maintain in the OT physical distancing, safety from droplets and aerosol are not easily done in the OT. In such a scenario and absence of a consensus on its treatment^{5,6} it is thought that laparoscopic surgery is probably more dangerous to cause the spread by generating more aerosol inside the OT.^{7,8} In such a situation we have looked into the available literature and are accumulating some tips and tricks to avoid the risk of spreading the disease from the OT environment.

MATERIALS AND METHODS

A total number of 699 cases collectively in all the three institutes and the sister centres in most of the corners of Assam were operated upon during the period from 01.04.2020 to 16.06.2020. The HAMM group with its four sister centres situated in the rural Assam led from the front with highest numbers (368) of operations in these four study institutions. Team Apollo from the city of Guwahati, the gateway to North-East India did well too with 95 cases. Jorhat Medical College did well with full academic standard and follow up of various guidelines issued by the ICMR, MOH and the Government of Assam. It behaved like a responsible teaching Institute, teaching its students the standard, protocols and developed their SOP and above all not be afraid of the disease. It performed 70 procedures during the period including several laparoscopic procedures. Nazareth from Meghalaya, Shillong did 166 operations with over 38 laparoscopic procedures.

Team Dr AK Deb from Apollo Hospital, Guwahati shared their experience. A detailed analysis of the centre is available with representation graphs and statistical diagrams. A total of 95 cases were operated from the 1st of April 2020 to 16.06.2020. 75 patients underwent laparoscopic procedures and the rest open procedures under general anaesthesia (Figure 1).

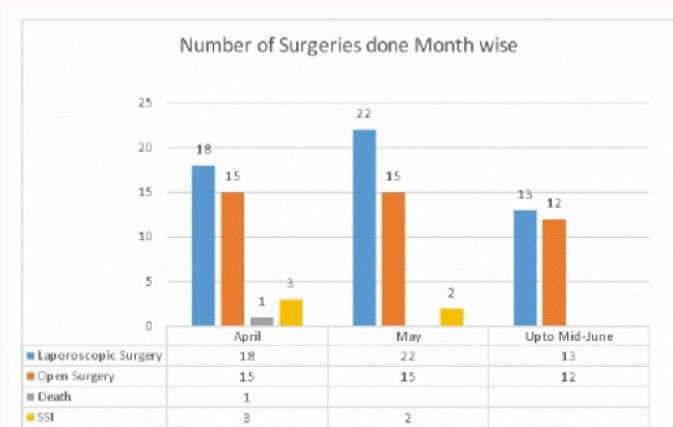


Figure 1 Number of surgeries in Apollo Guwahati in the study period

Inclusion criteria: The patients were taken after confirming symptomatic negative as per the WHO criteria. The operation team did not have access to rRT PCR COVID-19. Preventive measures were applied. It included PPE, N95 masks and

Face shields for all operating procedures for all the People inside the OT for laparoscopic procedures, the Trocar and cannula were checked for leaks and worn our washers as well as tired cannulas. Defective types of equipment were discarded. Savlon water seal drainage (Innovation by the team) was made universal for all laparoscopic procedures for the release of gas (Figure 2).



Figure 2 Exhausting CO2 through viricidal solution

Follow-ups of over 14 days did not show any COVID 19 spread on any OT Workers and patients.

It can be safely taken as a model of safety as the procedures were undertaken at a time when no testing facilities were available and the pandemic was showing its ugly head strongly and defiantly.

Team of Dr Jayanta Das from the Nazareth Hospital in Shillong in the same period performed a total number of 166 Major operations. Their Laparoscopic rate was 40%. It included some complex procedures, taking over two hours of O.T time. Dr Das and his team maintained an SOP in their OT. Nazareth Hospital did not have the facility to check the rRT PCR COVID 19 in all patients preoperatively. Patients were restricted to need basis and selective approach was followed. The patient screening was done by detailed history. Anyone having contact history with a COVID 19 patient was operated in a dedicated COVID 19 specific operation theatre. Full body PPE kit was used and stricter precaution for stopping the spread of the infection for these operations.

However, when normal operation theatre was used, they maintained a definite SOP too as routine Chest skiagraphy of the patients for operation on a preoperative day. Least possible number of peoples was allowed inside the operation areas. Patients were taken in with a three-layered mask on. Regional anaesthesia like Thoracic epidural, spinal and regional blocks preferred wherever feasible. When intubation is needed the Endotracheal tube is clamped till connected. The anesthetist uses N95 masks, Face shields, Disposable gown and Mcintosh. OT Floor repeatedly mopped with Viricidal solution.

surgeons wear N 95 masks, goggles, plastic disposable aprons and below knee length non-disposable boots. The surgeon enters once the patient is anaesthetized and ready for the incision. During the procedure, diathermy is used minimally and the smoke is simultaneously sucked. It goes to the suction container which contains Viricidal solution. During laparoscopic surgery, the set up uses a side channel to evacuate the smoke into a Viricidal solution as in water seal drainage system. Suction goes to the Viricidal containing bottle. Pneumoperitoneum is reduced totally under vision at the end of the procedures.

Dr Chaidul Islam and his team in their various hospitals undertook 368 major operative procedures. Their average procedures were divided between lap and open procedures as 75% and 25% respectively. The team went by meticulous history to find out the history of fever, cough, sore throat, diarrhea in the last three weeks. As a precautionary measure, if any of those found in the history, the patients were advised to wait for three weeks and taken up for surgery after the wait is over and the patient is cleared of those complaints. They did not do any modification in their OT. The team initially started with full PPE kits during procedures. After 40 consecutive cases, they scaled down the PPE to N95 masks, face shields, Mcintosh and shoe covers.

A follow up of over 14 days showed no COVID 19 on any of the treating team or the patients so far. However, a word of caution here, it is better to comply with the barriers till such time the tests are available.

The Jorhat Medical College performed 70 operations during the time. Initially, laparoscopic procedures were not undertaken for there was the report of higher aerosol generation due to Carbon Dioxide insufflations, leakage and deflation. The laparoscopic procedures started once reports from some reliable world bodies suggested that there were no additional risks involved. The precaution was taken, discussed and followed in the department systematically as the institute is a post-graduate teaching institute and the trainees are guided accordingly. Jorhat Medical College erected a model. As we had a Viral Laboratory, we had the privilege to get the rRT PCR COVID-19 testing done preoperatively. We had an SOP in place from very early on.

1. Desperate emergencies like shattered spleen; we went in after sending rRT PCR. Did not wait for the report. Open surgery with the full team, constituted with the least number of persons inside the operation area, under the available complete hooded PPE and face shields (**Figure 3**).

2. In certain cases where a preoperative time is possible, like a perforated hollow viscus or acute appendicitis or a strangulated hernia, we waited for PCR report and if negative, we could go in with N95, face shields, goggles, Mcintosh. If positive with full PPE. But we did not have any positive patients to operate upon.

3. Elective cases. We started slowly. Being a Government facility with COVID hosting, we had to reserve our manpower. Once we started, we followed the SOP for it again.



Figure 3 With Full PPE protection in indeterminate and COVID 19 Cases

The SOP prepared as Patients were screened in the triage area. A good history to exclude contact to COVID 19. Patients with Fever cough and travel history were sent to Pulmonologist for screening.

Fresh Investigations were done (Chest X-RAY). PAC by the team anaesthesia, if cleared then. The patients were asked to be admitted on the day of giving swab for rRT PCR

No contact with outsiders without screening. Only Negative patients were taken up for surgery. The reports of severe postoperative complications if procedures done in COVID 19 illness made us avoid those. Open cases are performed as per the guidelines initially. We had some small modifications in the environment of the OT An exhaust fan would always be on as negative pressure OT was not easy to erect. The outgoing air is supposed to pass through a continuous film of 1% sodium hypochlorite solution. Full PPE were made available for all and anyone could use it at will. N95 Masks for all entering the complex. As in the case of Apollo, Guwahati, all Washers of the laparoscopic cannulas were changed to the tight-fitting one. The gas outline was passed



Figure 4 Povidone iodine-soaked gauze in all leak areas

through a bottle of 70% alcohol (Water seal drainage). One set was good for three cases at least. We changed only the drip set line (**Figure 4**).

The suction bottles (if central suction was not working) had 1% Sodium Hypochlorite solution to prevent viral aerosol. All the vents had PVP-I coated moistened gauge cover to stop the viral spread to the team.

Team anaesthesia used a specially designed shield box (**Figure 5**) for the introduction of the endotracheal tube. At times video endoscopy was used. 3 Micron HEPA filters were used to protect the anaesthesia stations.



Figure 5 Shield for the Intubation

On follow up of 14 days: No surgical team members or anesthesia team members or any patients were infected from the OT.

RESULTS

It is said that the virus will stay. Like HIV, we need to take care to prevent its spread. The spread can be blocked if small steps are taken in the operating environment.

A stepwise generated SOP from the above materials and methods in various settings to avoid the spread of COVID 19 now in both rural as well as the urban areas can now be enumerated. Soon testing facilities, which are reliable and fast, will be available widely. It would be wise to test the patients for the presence of COVID-19 preoperatively. Till such times-

1. Contact history of the attendants must be taken.
2. The patient stays in the ward after giving a sample for the tests.
3. A chest skiagram the day before the day of surgery is a cheap, quick and reliable objective evidence against

the COVID-19 presence on the patient.

4. Routine pre-anesthesia-checkup (PAC) procedure will do.
5. All patients must be taken to OT with a triple-layered mask on.
6. Minimum utilization of manpower is expected. However, in teaching institutes, the learners must be made to follow the safety procedures strictly.
7. OT environment need not be negative pressure. Continuous airflow has shown to reduce the viral load on an ambulance carrying open COVID-19 patients. So, an exhaust fan which will throw out the air through a film of 1% sodium hypochlorite solution is safe and non polluting to the environment outside the OT.
8. The central suction unit will release the air through a viricidal solution into the environment.
9. The inside suction apparatus will have 1% sodium hypochlorite solution too.
10. Surgeons, anesthesiologists, assisting sisters and circulating nurses along with the multipurpose workers must use appropriate PPE like N-95 mask, plastic aprons, disposable boots, caps, face shields or goggles.
11. 3 Micron High Efficiency Particulate Air (HEPA) filters in the inlet and the outlet of the anaesthesia tables are a must.
12. All laparoscopic trocar and cannulas must be tight-fitting and without air leak.
13. A side vent must be used to release carbon dioxide through a water seal drainage kind of system through a viricidal solution. The bottle can be used multiple times; the tube needs change in each case.
14. All cannula mouths must have a protective wrap-around with 10% povidone-iodine soaked gauge which should be moistened in the interval.
15. The end, the release of gas must be done under vision.
16. The main surgeon is responsible to check the gas bubbling out through the system.

Below is the model of guidance that can be suggested in the rural surgical set ups.

Till such times the testing facilities and vaccines are available, meticulous history to find out the history of fever, cough, sore throat, diarrhea and loss of smell in the last three weeks are of importance.

If any of those found in history, the patients are advised to wait for two weeks and taken up for surgery after the wait is over and the patient is cleared of those complaints.

In such a backdrop, no modification in OT is necessary. N95 masks, face shields, plastic apron and shoe covers are found to be enough as barriers.

DISCUSSION

On analyzing the experiences of the various hospitals in

different setups and different states it was easy to find that all the surgeons were concerned with patient safety too. The institutes may not have a documented SOPs in place but had a strong disciplined practice in place. The number of surgeries was not negligible. Considering all the procedures were need to have a basis, it was indeed a great effort. All procedures were undertaken when the death rates in the western world were scary and in India too it was spreading like wildfire.

We find three distinct models here. One the rural set up under the leadership of Dr Chaidul Islam of HAMM group of Hojai, a small rural town in central Assam. It had four more sisters concern in the western Assam in the rural Town-ships. Their principle fits with the presently available data, which suggest that COVID-19 is more active in the cities. Their model can safely be applied to any rural setting with individual SOPs in place.

We have another semi-rural but academic institute background here. The Jorhat Medical College, department of surgery is a postgraduate training department, set up in a semi-rural background. Jorhat being an important town in the upper Assam is in a rural ambience. From the day the pandemic was declared, the department, sat down and prepared an SOP of surgery and distributed it to all. Being a postgraduate teaching institute is needed to adhere to the teaching standards and it did so. So, whenever the procedures started, we never had any confusion about what to do.

We have here another model from the capital city of Meghalaya, Shillong. One of the busiest tourist spots in the world. The Nazareth hospital is one of the oldest healthcare institutes in the North East of India and a missionary one. They had an SOP in place and it was found to be having components common to the institutes working in urban areas.

Finally, the Apollo Hospital in Guwahati. Dr AK Dev and his team had an SOP in place and did several surgeries guided by their protocol successfully. No team reported any COVID-19 spread to any HCWs or patients within 14 days of post-op follow-ups.

CONCLUSION

It was a good and welcome move by different operating teams in varied backgrounds in the North East India to join hands to develop a plan of the operating environment in North East India for both the rural as well as the urban settings. All had innovations in place. All had shown a commitment to their procedures and held up the principle of “Primum -Non-necere”. At the end, a real procedural SOP could be obtained which demarcated the rural as well as the urban differences. The model can safely be designated as the ‘**Assam Model of safety in COVID-19 times surgery**’. We offer the SOP to anyone who wants to follow and no copyrights to whatsoever we suggested in this paper. Let mankind win.

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Contribution of authors: The study was conceived, designed by Dr Narendra Nath Ganguly MS, PhD, Associate Professor and in-charge of the Department of Surgery, JMC, Jorhat. We declare that this work was done by the author(s) named in this article and all liabilities about claims relating to the content of this article will be borne by the authors.

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ORIGINAL RESEARCH PAPER

Prevalence of hypertension among obese and overweight students in the schools of Silchar, Assam

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ABSTRACT

Introduction: Hypertension, a silent killer disease, once thought to be a disease of adult population, now studies have shown that the process of development of it starts in adolescence perhaps in early childhood. There has also been increased prevalence of overweight and obesity in school children in developing countries including India. Obesity is one of the many risk factors of hypertension, metabolic and cardiovascular diseases. **Materials and methods:** 1000 school children of aged 10-16 years were screened for hypertension, overweight and obesity. Using BMI and WC as per IAP chart, school children were categorized as overweight, obese; and blood pressure were measured by mercury sphygmomanometer. Definition and stages of hypertension were taken as per American Academy of Pediatrics guidelines for childhood hypertension 2007. **Results:** The prevalence of hypertension in the present study is 9.6%. The mean age of study population is 14.68 ± 1.02 years. The prevalence of hypertension in male and female was 11.5% and 8.08% respectively. 11.5% children were overweight and 6.3% were obese. Stages of hypertension were found, elevated BP 2.1%, stage 1 hypertension 6.1% and stage 2 hypertension 1.4% in the overweight and obese students together. **Conclusion:** Although hypertension is a well monitored and well versed disorder among the adult population yet it is the cheer expectancy of this disease among pediatric population which is threatening. A substantial number (9.6%) of overweight and obese school children had different categories of hypertension in our study. Time trends in childhood obesity, hypertension and their consequences should be monitored for primary prevention of adult hypertension.

Keywords: Obesity; overweight; hypertension; BMI.

INTRODUCTION

The prevalence of overweight and obesity among children and adolescents has widely increased worldwide. Although once considered to be a major problem in affluent countries only, overweight and obesity are now rising all over the world even in developing nations like India and has been called a global epidemic.^{1,2,3} This may be due to ongoing urbanization and economic transitions. Obesity and overweight are also major risk factors for non communicable diseases many of which have now been grouped under heading of metabolic syndrome as these diseases have been seen to occur together.

In concert with this increasing prevalence of overweight and obesity, anecdotal evidence suggests that pediatric hypertension may also have become more prevalent than previously reported. This increase reflects an epidemiologic shift from secondary hypertension (most often caused by renal disease) to primary (i.e. essential) hypertension as the main cause of hypertension in the pediatric age range.⁴ Elevated blood pressure has been established as a major risk factor for the development of cardiovascular disease.⁵ Obesity in infants and adolescents is acquiring epidemic dimensions and is a major risk factor for metabolic syndrome (MS). MS consists of a group of metabolic abnormalities and according to the International Diabetes Federation (IDF) characteristics

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of this syndrome include obesity with emphasis on excess abdominal fat, hypertension, dyslipidemia and hyperglycemia.⁶ Primary hypertension as a part of metabolic syndrome has become rampant among obese and overweight children with their own set of complications. Ethnic differences in blood pressure are seen as among African Americans, Hispanics, Asians. Asians are more prone to these adverse effects of overweight and obesity like hypertension making these studies very important among these ethnic groups.

Keeping in mind that the young school children who are obese and overweight but apparently healthy may have hypertension, the present study was undertaken to find out the prevalence of hypertension in students of 10-16 years of age of schools of Silchar town, Assam.

MATERIALS AND METHODS

This school based study for screening of hypertension among overweight and obese school students of aged 10-16 years of class VII-X standards of schools of Silchar town, Assam was undertaken over a period of 4 months from August 2019 to November 2019. This period was chosen because the schools were free from examinations during this period. 1000 high school students from 2 government and 2 private schools were included in the study. Students with known chronic diseases like epilepsy, renal, endocrine diseases found on school records and physical examination and not willing to participate were excluded from the study population. As this is a short duration study lacking follow up, we did not consider determinants like, diabetes, IHD, ethnicity, food habit, substance abuse. Schools were notified the date of screening and for consent of the parents/students in advance with explanation that the procedures to be used are non invasive and the purpose of the screening. In the selected

schools, by random sampling the enrolled students underwent for measurements for height, weight and blood pressure. Datas were recorded in a pre-structured proforma. BMI was calculated and matched as normal, overweight or obese according to the IAP Chart for BMI for age from 5 to 18 years.^{7,8} The stages of hypertension and definitions were taken from the AAP Guidelines for Childhood Hypertension, 2017.⁹

RESULTS

Out of 1000 school students 493 (49.3 %) were male and 507 (50.7%) were females. School wise, 514 (51.4%) students were from private schools and 486 (48.6%) were from government schools. The mean age of students were 14.68 ± 1.02 years (Table 1). Out of the study population 115 were overweight (11.5%) and 63 were obese (6.3%) (Table 2). Out of 493 male students, 55 had hypertension (11.5%) and out of 507 female students, 41 (8.08%) were hypertensive.

Table 1 Age, gender and school type wise distribution

1.	Gender n (%)	Male 493 (49.3)	P value >0.05
2.	Age (mean) in years	Female 507 (50.7) 14.68 ± 1.02	
3.	School type		
	Government	486 (48.6)	
	Private	514 (51.4)	

Table 2 Gender and school type wise distribution of obesity and overweight

	Gender, n		Total n(%)	Type of school, n(%)	
	Male	Female		Private	Government
Overweight	52	63	115(11.5)	74(7.4)	41(4.1)
Obese	32	31	63(6.3)	33(3.3)	30(3.0)

Table 3 Prevalence of overweight and obesity according to type of school

School type	n	Over wt, n(%)		Obese, n(%)		
		BMI	WC	BMI	WC	Wt/Ht
Govt.	486	41(8.4)	54(11.1)	30(6.1)	25(5.1)	45(9.2)
Private	514	74(14.3)	62(12.0)	33(6.47)	50(9.7)	72(14)
CHI SQUARE TEST		P<0.05 (0.003)	p>0.05 (0.63)	p>0.05 (0.87)	p<0.05 (0.005)	p<0.05 (0.01)
ODD'S RATIO		1.7	—		1.9	1.6

Table 4 Overweight and hypertension.

Stage of hypertension	Number of overweight students (<i>n</i> =115), <i>n</i>
Elevated blood pressure	13 (11.3)
Stage 1 hypertension	34 (29.5)
Stage 2 hypertension	10 (8.69)

Values in parenthesis denotes percentage.

Table 5 Obesity and hypertension

Stage of hypertension	<i>n</i> (number of obese students=63)	Neither overweight nor obese (<i>n</i> =822)
Elevated blood pressure	8 (12.69)	20 (2.4)
Stage 1 hypertension	27 (42.8)	12 (1.4)
Stage 2 hypertension	4 (6.34)	2 (0.2)

Values in parenthesis denotes percentage.

DISCUSSION

The overall prevalence of hypertension in the present study is 9.6%. The prevalence of elevated blood pressure were 21 (2.1%), stage 1 hypertension were 61 (6.1%) and stage 2 hypertension were 14 (1.4%). The prevalence of hypertension was more in male than female students (11.5 vs 8.08%) and obese and overweight students than normal build students (Table 4 and 5). Studies done by Mahanta TG et al.¹⁰ found significant higher mean blood pressure values among overweight and obese school children as compared to non overweight and non obese children. Nirav Busch et al.¹¹ in a study done in Surat, India found a prevalence of hypertension of 6.48% and the prevalence of obesity among the hypertensives to be 8.7%. Our prevalence of hypertension is slightly higher than this study because the number of students included in the study was more from private schools than the government schools. The private school goes the odds of becoming overweight are 1.7 times more than the government school goes (Table 3). There is no denying of the fact that the private school going students have more access to higher eat outs and a sedentary lifestyle. In another study in Shimla by Avinash Sharma et al.¹² revealed rates of elevated blood pressure significantly higher (46.5% vs 17%, $p < 0.001$) among those with high BMI (overweight and obese) compared to those with normal BMI with a total hypertension prevalence of 20% which is comparable to the present study. Other studies compared the prevalence of metabolic syndromes among children with increased BMI and have found the prevalence of hypertension to be more among obese and overweight.^{13,14,15} Hypertension is also a part of metabolic syndrome.

CONCLUSION

Although hypertension is a well monitored and well versed disorder among the adult population yet it is the cheer

unexpectedness of the disease among pediatric population which is threatening. A substantial number (9.6%) of overweight and obese school children had different categories of hypertension in our study. Time trends in childhood obesity and hypertension and their consequences should be monitored for primary prevention of adult hypertension. The limitation of our study is that we could not follow up the children included in this study for serial monitoring of blood pressure and the duration of the study is also short.

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Abbreviation: BMI (body mass index); WC (waist circumference); Ht (height); AAP (American Academy of Pediatrics); IAP (Indian Academy of Pediatrics).

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CASE REPORT

Neglected posterior hip dislocation: management of an 18 years old female

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ABSTRACT

Neglected traumatic dislocations of the hip are one of the disabling condition in lower extremity which is seldom found in adults. Also, it is not an uncommon condition seen in developing countries. Its treatment is often difficult and controversial. Here we present 18 years old female who presented to our hospital with 7 years old posterior hip dislocation sustained following fall from a bicycle. She had gone through multiple treatments for her dislocated hip without any success. The patient was managed by Girdlestone osteotomy and skeletal traction followed by total hip replacement (THR) with uncemented acetabular cup and cemented femoral stem. Her Harris hip score improved from 48 (preoperative) to 87 (postoperative). On follow-up, she had a good range of movement of the hip with no pain, deformity and limb length discrepancy. Girdlestone osteotomy and skeletal traction followed by total hip replacement (THR) provide promising results in neglected hip dislocation.

Keywords: Girdlestone Osteotomy; Total Hip Replacement; Harris Hip Score.

INTRODUCTION

Neglected traumatic dislocations of the hip are rare in adults. However, in developing countries, unreduced traumatic dislocations are not uncommon. They are usually the result of a motor vehicle accident, often combined with multiple trauma including head injury, fracture of the ipsilateral femur or bilateral injuries, which may detract attention from the dislocation.¹ Neglected hip dislocations occur in situations when the patient does not or cannot seek adequate medical care. As such, chronic dislocations may be observed in patients with high pain tolerance, patients with the decreased cognitive ability to recognize or verbalize their pain and patients with

additional injuries that are more obvious or life-threatening.²

In developing countries, patients usually attend hospital many days after trauma, having often received alternate therapy before. Treatment of neglected dislocation of the hip becomes more difficult to manage as time progresses because of the soft tissues contractures, adhesions, fibrofatty tissue filling of the acetabulum, and presence of myositis ossificans.³ Reduction of neglected dislocation of the hip is not only difficult but results in avascular necrosis and arthritis. Total hip replacement (THR) is recommended for hip dislocations with a duration of more than 3 months.²

A complete understanding of the factors that play a role in the aetiology of the instability of hip and a clear knowledge of treatment options are mandatory for the surgeon tackling this injury. Girdlestone osteotomy and skeletal traction followed by total hip replacement (THR) is a viable option for neglected dislocation hip.

CASE REPORT

18 years old female sustained a fall from a bicycle, resulting in an injury of her left hip, causing pain and an inability to weight bear. She saw a local doctor, who diagnosed a dislocation of her hip and attempted a reduction, which failed, as the hip remained painful and unstable. Six-months after the injury, the patient consulted an orthopaedic surgeon, who

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advised to undergo an open reduction of the hip, but patient abandoned treatment.

MANAGEMENT

We saw this patient 7 years after the initial injury complaining of hip pain. She was walking with an antalgic gait and had a decreased range of motion of her hip. The limb was in fixed adduction and internal rotation. She had a leg length discrepancy due to 5 cm shortening of the left lower extremity. Her hip movements were restricted and painful. Radiographs confirmed a persistent dislocation of the hip, with a false acetabulum in the left supra-acetabular region as shown in **Figure 1**.



Figure 1 Pre-operative x-ray of the pelvis with Both Hip showing neglected left posterior hip dislocation

Initially, open reduction was planned for this patient with 2 weeks before skeletal traction. During surgery, we encountered soft tissues contractures, adhesions, fibrofatty tissue filling of the acetabulum, and irregular sclerotic cortex with enlargement of the femoral head. This anatomical distortion made it almost impossible open reduction of hip. We decided to clear the acetabulum of fibrous tissues and did Girdlestone osteotomy and soft tissue release (**Figure 2**). Postoperative skeletal traction with increasing weight was

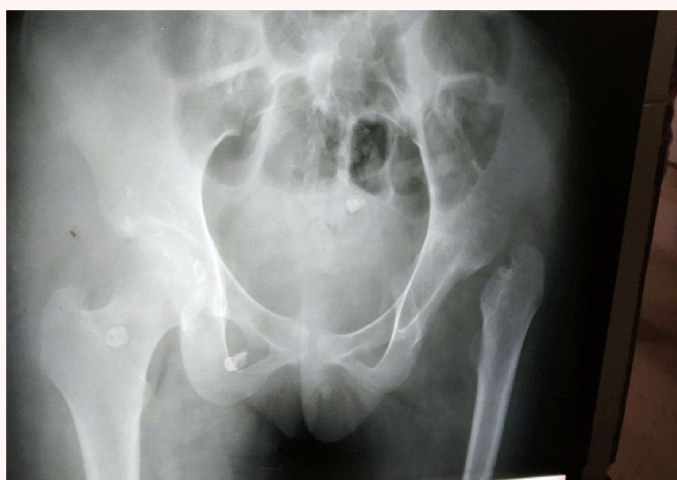


Figure 2 X-ray of the pelvis with both hip after the first operation, showing post-Girdlestone osteotomy and skeletal traction

given for about 2 months and serial weekly X rays were done. Traction was ceased when the greater trochanter was drawn at the level of the articular surface of the acetabulum (**Figure 3**). Then THR was done with uncemented acetabular cup and cemented femoral stem with prophylactic proximal femoral encircle (**Figure 4**). The leg lengths were equalized, and the postoperative recovery was uneventful. Roentgenograms showed satisfactory position and fitting of the prosthesis.



Figure 3 X-ray of the pelvis both hip after the greater trochanter was drawn at the level of the articular surface of the acetabulum

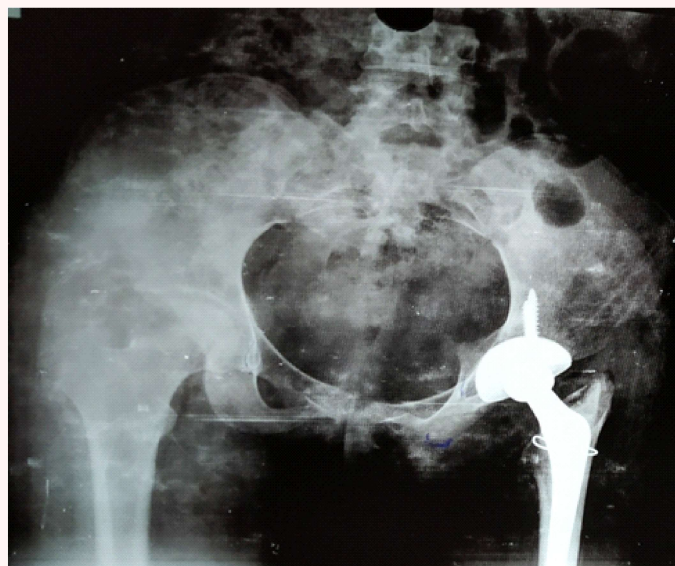


Figure 4 Post-operative pelvic both hip X-Ray of the patient after total hip replacement

Her physiotherapy was started soon postoperatively, and she was discharged on the fourteenth postoperative day. Her functional status improved on every successive follow-up visit, and the HHS score improved from 48 (preoperatively) to 87 (postoperatively). She had no pain, a mild residual Trendelenburg gait due to her abductor insufficiency and excellent function.

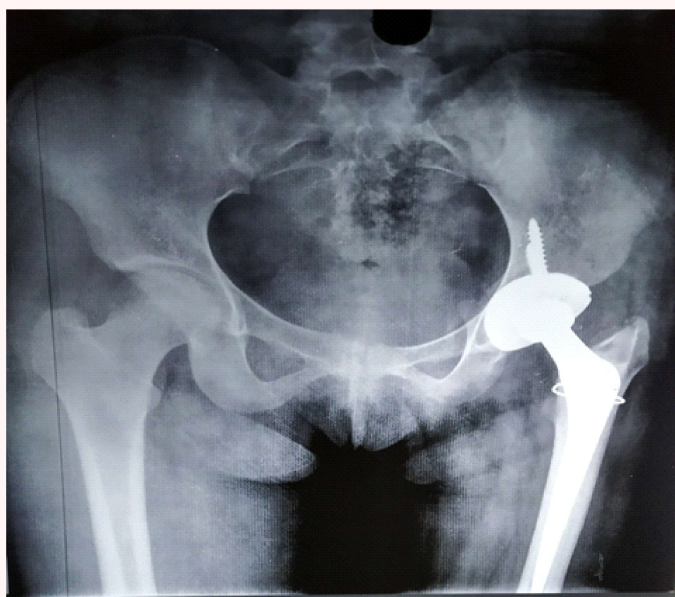


Figure 5 Three months Postoperative follow up pelvic X-Ray of the patient after total hip replacement

DISCUSSION

The ongoing discussion of the best treatment option for the management of neglected dislocation hip continues and remains controversial. Various studies reported different methods for operative treatment of neglected fracture-dislocations including the use of a sub-trochanteric osteotomy, the Girdlestone procedure, hip arthrodesis, hemiarthroplasty and total hip replacement.⁴ All these procedures have their merits and give different outcomes. The results can be further altered by avascular necrosis of the femoral head which occurs in more than 50% of these cases. Garrett et al.² have recommended total hip arthroplasty for hips with posterior dislocations classified as type IV (fracture of the acetabular rim and floor) or type V (fracture of the femoral head with or without other fractures) with dislocations for more than 3 months.

Pai recommended reduction under anaesthesia for patients where a dislocation had occurred three days to three weeks previously.⁵

Banskota et al.,⁴ in their study of eight cases with neglected posterior dislocation on hip reported good results in three cases treating the hip with an open reduction. They achieved a mean Harris hip score of 89 (range 84–96). Leg lengths were within 2 cm in seven of the eight cases, and one patient had a discrepancy greater than 2 cm.

Verma et al.,⁶ in his study of 14 cases neglected dislocation ranging from 14 days to 1-year duration performed open reduction and reported excellent results in four cases, but also had poor outcomes in five cases.

In a study conducted by Berend et al.,⁷ using a constrained THR, ten per cent were primary hip replacements in patients with an abductor dysfunction secondary to trauma or neuromuscular disease. They reported promising results,

which would indicate that constrained THR to be a viable alternate option with abductor dysfunction with a high dislocation risk.

In a study conducted by Paavilainen et al., 100 cementless total hip replacements in 52 severely dysplastic and 48 dislocated hips, with some new technical solutions to the problems involved. In hips with tight flexor and abductor muscles or with deformities of the proximal femur, various osteotomies were performed. Final results were the generally good limited correction of limb length discrepancy may be achieved with THR.⁸

Patel et al., presented a case of 30 years-old male patients with neglected hip dislocation. The patient complained pain in the left hip for 2 years with fixed deformity of the hip, with a history of fall from a tree 15 years ago. The radiographs showed an obturator dislocation of the hip with obvious pseudo-acetabulum around the dislocated femoral head. Uncemented total hip arthroplasty was performed and after 2 years follow up, the patient was able to walk unaided without pain.⁹

Ilyas et al., treated 15 patients with chronic unreduced hip fracture-dislocations result from motor vehicle injury at King Faisal Specialist Hospital and Research Center. All underwent 1-stage total hip arthroplasty with bone grafting and then monitored for 36-96 months range. Although there were 2 dislocations, 1 transient peroneal nerve palsy, and 1 superficial infection, generally all patients had significantly decreased pain, increased function, and increased range-of-motion scores using the Merle d'Aubigné scoring system.¹⁰

Kumar et al., reported a 31 years old female patient with neglected hip dislocation. The initial injury was 2 years before the patient's presentation to the hospital and had gone through many multiple treatments for her disease without any improvement. The patient was treated by constrained total hip replacement, resulting in improvement of Harris Hip Score from 48 to 81. On follow up, the patient showed improved range of motion of hip joint without pain.¹¹

CONCLUSION

Our case of 7 years old neglected dislocation of the hip treated by Girdlestone osteotomy and skeletal traction followed by total hip replacement (THR) with uncemented acetabular cup and cemented femoral stem total hip replacement which improves the patient's functional status successfully. Despite gaining 5–6 cm of limb length, the sciatic nerve was unaffected which is indirectly favouring Egli et al.,¹² who found no correlation between the amount of lengthening and sciatic nerve palsy in a large study on THR.

We have not found any other case report with a 7-year-old neglected dislocated hip with contractures of the stabilizing muscles and pseudoarthrosis, as in our case, having achieved a satisfactory conclusion.

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CASE REPORT

Lymphatic damage by mechanical trauma in hand and pension benefit concession: case report from Brazil

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ABSTRACT

The case presented consisted of one of the medical assistance expert's reports in the scope of the Federal Court and reached the grant of benefit-sickness benefit with subsequent conversion to retirement. Noticeable was the unusual nature of the mechanical trauma, considering that the forceful action did not receive more attention initially because of the small intensity of the applied force and the reduced extension of the anatomical area affected. The incapacitating damage was of lymphatic order in the dominant hand. The methods of qualitative exploration of the data made available in the case file and literature review were used for the analysis. The objective is to present an unusual condition in which the damage dispenses verifications through imaging tests and, in itself, allows the establishment of a causal link. The conclusion was that the collection of professional data, a history of the alleged incapacitating condition and a well-performed physical examination suffice to reach a conviction about the need to grant social security benefits in cases such as this.

Keywords: Lymphatic oedema; compensation; social security benefit; causal nexus.

INTRODUCTION

The work of medical expert analysis in the social security scope aims to reach the perception of some condition(s) capable of determining, among other conditions, incapacitation for work. Several diseases or traumatic sequelae can be seen and their relationship with the data of professional profile makes it possible to understand or not the occurrence of a state of incapacitation that can be total or partial, permanent or temporary. About the concrete case to be presented, it is inserted in the social security context employing a lawsuit

against the INSS, since in the medical examination of that body there was no evidence of the incapacity for work usually exercised by the applicant. Thus, the judicial appeal required a new expert assessment, which will be duly described in this case report. For this, the expert of the case made use of a detailed anamnesis of the factual situation that culminated with the alleged incapacity, professional analysis and specific physical examination of the lesion and its repercussions on the victim's work status. The damage seen was due to mechanical trauma. At first, with no greater initial severity due to the small anatomical extent reached and the low impact suffered. However, the affected area consisted precisely of some vessel pathway of the lymphatic system, which eventually determined a large and limiting lymphatic oedema of the dominant hand—which, secondarily, resulted in ankylosis of the fingers. Based on the collected data, it was considered a permanent partial incapacity that due to the other aspects involved 53 years old victim with a dominant hand paralysis and no profile for inclusion in the Professional Rehabilitation Program—redirected the expert diagnosis for a situation of permanent total disability.

This paper reports a case of incapacity for work resulting from the trauma of a mechanical nature that, despite being of a partial permanent nature, resulted in an understanding of the occurrence of permanent total work incapacitation.

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METHOD

The information contained in this article was collected from the procedural documents and medical expert's report and literature review. The shortage of subsidiary data like image examination did not compromise the expert evaluation, given the unequivocal existence of alleged damage and its correspondence with the reported trauma. Work Accident Communication was drafted promptly. Thus, it was possible to establish the causal link properly.

Case report (Anamnesis)

MJP, 53 years old lady with incomplete first degree disability wanted a grant of sickness assistance, with subsequent conversion to Invalidity Retirement with the INSS– National Institute of Social Security. The benefit was denied as the inability to work was not found. The petitioner filed a complaint with the Federal Court (TRF1) against the INSS, alleging that she did not take advantage of the injury that prevented her from carrying out the manual movements. She needed sufficient manual forces for loading and unloading boxes. The victim is right-handed. While putting effort to cut plastic loops holding some boxes, she had slipped his knife with the detachment of his right hand and made the back of the same hand against the corner of metal furniture. She had the CAT registration promptly. Earlier she had a feeling of loss of muscle strength, marked swelling and intense pain. Not improving with the treatments undertaken – dressings, cold compresses followed by hot compresses and anti-inflammatory – progressed to the point of determining the paralysis of all the fingers of that affected hand, stagnating them. Also, oedema did not regress till eight months leading to a post-traumatic condition by classical mechanical action, with the probable affectionation of vessels of the lymphatic system – oedema – and of possible regional innervation. The grant of the requested benefit was considered appropriate and was installed with the Disease Onset Date and disability Start Date and beginning dates coinciding temporally due to the causal relationship between the trauma, the damage and the incapacitation resulting from them.

Physical Examination

Permitted with the preserved general state, without indication of systemic changes worthy of note, specifically, right hand with intense lymphatic oedema, associated with finger drop paralysis and determination of ankylosis of the same. The pincer movements were all impaired by the manual closing. No active movements of right-hand fingers were seen. The evaluated person is right-handed. Nothing else was noticed noteworthy.

Diagnostic hypothesis: Sequela of mechanical trauma determining probable lymphatic oedema and ankylosis of fingers of the right hand with association with possible damage of interosseous branch (Fig. 1). Another possibility is oedema itself restricting the mobility of the affected hand, with secondary paralysis due to the lack of regional musculature.

Exams lying down and/or presented: Being a person with

financial difficulties and dependent on care by SUS – Unified Health System, the records only had medical reports. No imaging evaluation of the vascular system, mainly lymphatic and by the electrophysiological study of the regional innervation was performed. All expert evaluations were based on historical data and physical examination.



Figure 1 Showing the damages of hand

DISCUSSION

The Social Security Law grants of sickness benefit with subsequent Retirement due to mental or physical inability. On the other hand, they are not able to have their hands reassigned or do not present a profile for inclusion in the Professional Rehabilitation Program (PRP).¹

It is mandatory to carry out the expert evaluation. As published in the media, “Before thinking about joining the INSS, the insured must file an administrative proceeding with the institute. It is only after the refusal that the beneficiary should bring the Judiciary.”²

It is understandable to analyse the harm in conjunction with occupation data and the possibilities of another occupation. It is only the possibility of professional rehabilitation that would allow the concession of the benefit in question.

In this case, the victim suffered a mechanical injury due to a blunt action on the right hand. This trauma resulted in

immediate regional involvement with intense oedema, ankylosis of fingers, the impossibility of palmar opening and pincer movements. Resulting oedema of chronic lymphatic type did not subside after eight months, with all possible treatment. Because she was financially weak, could not carry out further studies to investigate the case.

However, from the medical expert point of view for retirement purposes, such examination reports proved to be dispensable, since what was required was limited to verifying the damage – unquestionable in this case. Lymphedema, once instituted, leads to a chronic condition. (Mayall, 2000).³

Bergmann,³ reveals that the diagnosis of lymphedema can be obtained through subjective and objective criteria through history and physical examination.

Thus, it is confirmed that the method used in the expert evaluation of the case in question followed the dictates of a consensual protocol of a society of specialists and therefore, validated is how such verification of work incapacity proceeded. As for the causal aspects, Bergmann,³ citing Camargo (2000), said that these are due to external causes. Severe tissue lesions may lead to the development of lymphedema when they affect the structure and / or functioning of lymphatic vessels. Chronic venous insufficiency, when severe, may overwhelm the lymphatic system, or be associated with congenital insufficiency of the lymphatic vessels. In cases of recurrences of erysipelas, lymphangitis or cellulitis, lymphedema can be established due to infectious and inflammatory conditions.

Thus, external causes are capable of promoting direct affection of the local venous system with lymphatic overload, coupled with a secondary inflammatory process, are sufficient for the development of lymphatic oedema and its consequences. And on lymphedema, it further stresses that acute forms are temporary conditions without skin alterations. Chronic being the common form is usually insidious, with the absence of pain, not being associated with the erythema. Chronic lymphedema is irreversible.

It was well established that the understanding of chronicity was achieved by the fact that eight months had elapsed since the beginning of the process, (since the limit of six months to the end of the acute phase was established).

Tacaniet al.⁴ confirm both the possible traumatic cause and the chronicity aspect, as Lymphedema is a chronic, severe and progressive condition characterized by the accumulation of proteins in the interstitium due to deficiency of the lymphatic system, which may be due to congenital abnormalities of the lymphatic vessels (primary lymphedema) or acquired, such as trauma, lesions, lymphadenectomies or infectious and chronic diseases (secondary lymphedema). A possible diagnostic method is related to Lymphoscintigraphy which can be interpreted in three ways: quantitative, which evaluates the transport of the radiopharmaceutical about time; qualitative, which visually analyses the images; and semi-quantitative, that associates data of the radiopharmaceutical

transport dynamics with the time of onset of radioactivity. The qualitative evaluation is one of the most used in the interpretation of lymphoscintigraphy with 70 to 94% of sensitivity and 100% of specificity, presenting accuracy greater than 90%. In this study, we opted for qualitative evaluation, due to the high specificity and ease of visual interpretation of lymphoscintigraphic images.⁵

This test has a high cost and thus impossible for patients who depend on their achievement through a vacancy with the SUS. As for the aspects of the proposed neurological injury, the radial nerve has a motor branch responsible for innervation of the triceps, and the radial long and short extensors of the carpus for the movements of the fingers and, if injured, causes the inability to extend related body segments. The NIP is a motor branch of the radial nerve. It has six sub-branches, which are responsible for the innervation of the extensor digitorum muscles, the index extender, the long and short extensor of the thumb, the long abductor of the thumb, the supinator and the ulnar extensor carpi. The branch to the supinator muscle exits before the Froshe arcade, while the other branches emerge after the Froshe arcade. Because of this subdivision, Spinner divided the compression of the NIP into two types; type I, in which the compression of all the branches occur, and type II, in which the isolated compression of some branch can occur. The diagnosis of neurological lesions is clinical, it is part of the physical orthopaedic examination. In the examination, our patient presented the extension of the active wrist with radial deviation, since the radial extensors of the wrist are innervated by the radial nerve, but it was unable to extend the fingers and thumb, demonstrating a compromise of the posterior interosseous nerve, which is responsible by innervation of the common extensor of the fingers and the index finger, long and short extensor and long abductor of the thumb and ulnar extensor of the carpus.⁶

Since the diagnosis is clinical – physical examination – and does not depend primarily on any type of instrumental evaluation, it can be understood that in the present case the paralysis of the fingers of the right hand, in gout, can rather configure such an injury. However, we know that conducting an Electroneuromyography could contribute to this understanding, although its realization may suffer interference that may contaminate the results. According to Marchetti and Duarte,⁷ citings Enoka, electromyography monitor the electrical activity of excitable membranes, representing the measurement of the action potentials of the sarcolemma, with voltage effect as a function of time. The electromyographic signal is the algebraic summation of all the signals detected in a certain area and can be affected by muscular, anatomical and physiological properties, as well as by the control of the peripheral system and the instrumentation used to acquire the signals.

The dispensability of the aforementioned study seems clear since the history associated with the physical neurological examination is capable of identifying the damage and,

especially if we take into account that it is an examination that promotes painful discomfort for the patient and represents a high financial cost.

Thus the physical signs are compatible with the reports about the mechanical trauma suffered and in analysis with age, the low level of schooling and the professional aspects of the same point to their total work incapacitation and permanent, especially if we take into account the absence of a profile for the reallocation of labour or its inclusion in the Professional Rehabilitation Program (PRP).

CONCLUSION

The physical limitation was unquestionable and the history allowed the establishment of a causal link between the injury and the referred trauma. The physical evaluation was sufficient for an expert diagnosis of incapacitation at work. Neurophysiology and imaging tests proved to be dispensable both for the invasive nature and for the high financial cost they represented. The combined analysis of socioeconomic, physical examination and professional data led the expert reasoning for the occurrence of such incapacitation as being of a total and permanent nature, allowing the granting of the Sickness benefit with subsequent conversion to Invalidity Retirement with the INSS.

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CASE REPORT

Child abduction homicide by adolescent perpetrators: a rare case report

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ABSTRACT

Cases of child abduction and homicide though rare but are often overwhelming due to the public and media attention. While numerous studies on child abuse and neglect have been conducted throughout the country and worldwide, research on child abduction and homicide remains scant. We report such a case of a child who was abducted and eventually smothered to death by a couple of adolescent perpetrators. We also intend to better understand these types of child abduction homicides and to analyze strategies that will help to revamp the expertise into such criminal investigations.

Keywords: Child abduction; homicide, smothering; juvenile hate crimes; adolescents.

INTRODUCTION

Often children are found missing for a short period and they reappear on their own without any testament of foul play. Nevertheless, children do get missing against their prerogative. A majority of them do undergo traumatic and stressful experiences but are returned home alive without any serious physical anguish. A very small group of these abducted children are gravely victimized, either they are sexually molested or killed.

The list of children who are abducted and killed each year by someone who is a stranger is relatively small, compared to the number of missing children or other types of child murder. Worldwide there is approximately one child abduction murder for every 10,000 reported missing children.¹ In India, child abduction murder has a very low frequency of all murders committed. And even fewer children are killed by asphyxia, i.e., either by strangulation or smothering.

As the victims of child abduction murders are unique among murder victims, so too are their killers. About 1/10th of them are juvenile. But cases of juvenile hate crimes have become more prevalent over the past 25 years. This may be due to a drastic cultural and societal change which has been marked by a lack of a parent in the home providing guidance and/or poor peer selection.² Regardless, child abduction murders where the perpetrators are adolescents themselves are extremely few. And this makes our case unique and unexampled.

CASE HISTORY

A 4-year-old male child (**Figure 1**) was found lying dead near a bamboo forest at around 7 AM. The local people of the village informed the police personnel who identified the body of the subject. Incidentally, a missing report was lodged in the same Police Station on the previous evening with the child being missing from 4 PM. The post-mortem examination was arranged. On further investigation, two adolescent boys of 12 and 13 years respectively were nabbed by the police,

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and they admitted to having killed the child. The boys confessed that the child was playing with a costly mobile phone near his own house in the late hours of the evening. The two adolescent boys then lured him to a secluded place and took his phone from him. When the child started crying and shouting, the boys smothered him to death and disposed of the body in a gunny bag and kept it in the bamboo forest in the dark of the night.



Figure 1 The deceased child

AUTOPSY FINDINGS

The post-mortem examination revealed the subject was of medium built and was moderately nourished. Rigor mortis was present all over the body. On external examination, evidence of bluish discoloration was found over the nail beds, tips of fingers and lower lip. The tip of the nose was found to be flattened. Post mortem gnawing was found over both right and left lobules of the ear with the absence of both sided lower one-third of the ear lobules. Post-mortem gnawing over the left eye with partial evisceration with extrusion of intraocular contents was noted. Linear abrasions were found both on the right and left cheek. Abrasions were found placed over the left side of the chin adjoining the left labial commissure. One subcutaneous tissue deep bruise was found measuring 0.8" x 0.5" over the left side of the chin just below the left labial commissure. Bruises were also found diffused over the tip of the nose and inner aspects of the upper and lower lips with evidence of fracture of the nasal septum with extravasations of blood in and around. The abrasions were fresh and non-scabbed and the bruises were reddish. On

dissection, all the internal organs were seen to be congested. Multiple petechial hemorrhagic spots were found on the serous membranes in the thorax, lungs (**Figure 2**) and the pericardium. Forensic science laboratory gave a negative report for poisoning. Opinion as to the cause of death was given as death was due to effects of asphyxia resulting from smothering - antemortem in nature and homicidal in manner. It was further corroborated with the circumstantial shreds of evidence.

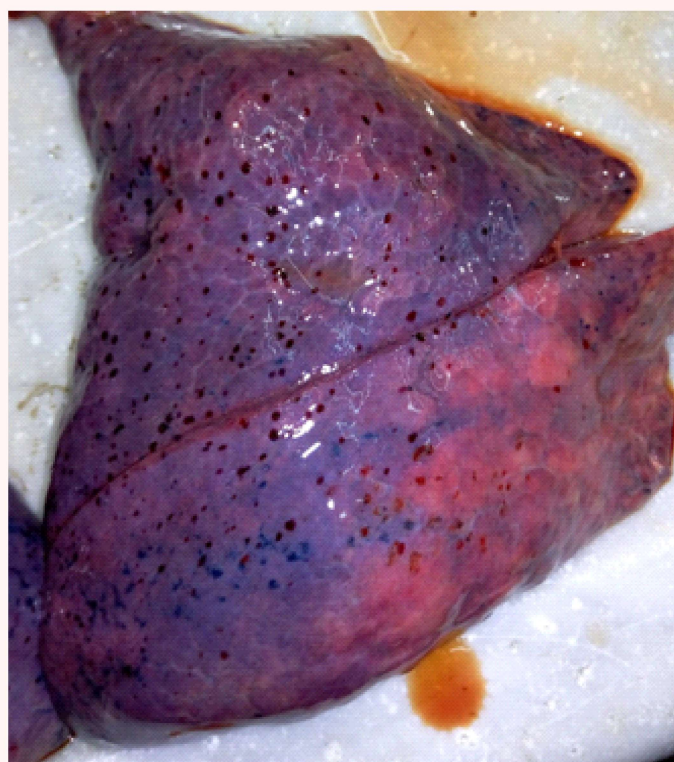


Figure 2 Petechiae on Lungs

DISCUSSION

Child abduction homicides are rare incidents and coupled with their complexity and emotion-laden nature and with the massive media attention, they are extremely difficult to investigate. Investigating officers should always earnestly deal with all reports of a missing child. They need to understand that children are vulnerable in a psychological sense. They are immature and innocent and hence are easily deceived by the offenders. A quick assessment of the nature of the case is to be made with all details surrounding the age of the child, history and circumstances in which the child was missing and then a thorough search to find the body as early as possible. And then to conclude requires a complete and meticulous autopsy and correlating the critical findings at autopsy with the exhaustive crime scene analysis and police interrogations and shreds of evidence. The pivotal aspect in the investigation of a child unexpectedly found dead coupled with suspicious findings, is to establish the accurate manner and cause of death and for a matter of fact all such cases should be considered a potential homicide until proven otherwise.

Smothering refers to a form of asphyxial death from mechanical occlusion of the mouth and the nose (external respiratory orifices), either by hands or by some foreign substances.³ Homicidal smothering is possible when the victim is incapacitated from drink or drugs, debilitated, suffering from ill health, aged or a child as in our case.⁴ But homicidal smothering of a child by adolescent perpetrators is sporadic and unique.

Prevention of juvenile hate crime requires an understanding of the hate crime perpetrator. Adolescence is a time of exploration and experimentation of the surrounding world as the individual strives to develop a sense of self. Hence, the goal should be to address the risk factors and to select the most appropriate form of treatment to minimize them. And as a society, it's upon us to look for the risk factors and warning signs in these adolescents who instigate hate crimes or commits murders. Most often than not, they have a history of conflict with parents and lack of parental affection and support, poor school performance, conduct or aggression problems, impulse-control problems, exposure to television violence or feeling of betrayal and underlying hurt.^{5,6,7} It is recommended that increasing self-esteem, establishing a close bond with the primary caregiver, and enhancing an individual's social and emotional skills along with psychological counselling will go a long way in reducing these rare events of adolescent homicides.⁸

CONCLUSION

Researches on child abduction and homicide are scant and when done suffer from geographical limitations. Further well-designed and large scales studies are needed to be carried out throughout the country to have a better understanding of the cases and have a statistical correlation of the socio-demographic characters and risk factors of children who are abducted and then killed. It would also provide an insight into the psychopathology of the offenders focusing on their psychiatric states and family backgrounds and help in

formulating a plan for investigation of child abduction homicides and their prevention by rapid action and proper investigation.

Conflict of interest: None declared.

Contribution of authors: We declare that this work was done by the author(s) named in this article and all liabilities about claims relating to the content of this article will be borne by the authors. Both the authors conceived and designed the study.

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REVIEW PAPER

Covid-19 and Cancer

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ABSTRACT

Coronavirus disease (COVID-19) has affected healthcare delivery all across the globe, particularly for chronic diseases like cancer. Everyday new literature and guidelines are emerging. In this review article, we aimed to discuss the essential insights of cancer care during COVID-19 pandemic. Cancer patients are at higher risk of morbidity and mortality from COVID-19. Yet they should not be deprived of necessary treatment while minimizing the risks of the spread of COVID-19 at the same time. Different recommendations about surgery, chemotherapy, radiotherapy and general cancer care have been proposed by different leading groups on how to deal with cancer during Coronavirus pandemic. Although these are troubled times with limitations in resources and challenges in providing healthcare, yet there is a need to evaluate cancer patients on case to case basis and deliver optimum care to all.

Keywords: SARS-CoV-2; cancer care; pandemic.

INTRODUCTION

The Coronavirus disease (COVID-19) caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) has emerged as the largest global public health issue of our era.¹ It originated from seafood and wet animal market in Wuhan, China in late December 2019 as a zoonotic virus transmitted to human by Chinese horseshoe bats.² However, within 3 months it spread all across the globe via rapid human to human transmission causing a large number of deaths.³ Subsequently, the World Health Organization on 11th March 2020 declared COVID-19 disease as a global pandemic.⁴ As of now, over 10 million cases and 500,000 deaths from COVID-19 have been confirmed worldwide

with the highest incidence and fatality reported from the United States of America.⁵ India ranks 4th in the list with total 548,318 confirmed cases and over 16,000 reported deaths due to COVID-19 till 29th June, 2020.⁵ In Assam, the largest north-eastern state of India from where we are writing this report, there have been 7,493 reported cases of COVID-19 with 11 deaths till now.⁵

The pandemic has severely affected the healthcare resources of the most developed nations. Medical facilities in Europe and America were so overburdened with Coronavirus cases that recommendations had to be formulated to ethically consider triage protocols by caregivers.⁶ In the absence of any definite vaccine or curative therapy for SARS-CoV-2, the only effective means to combat the disease spread was by isolating the diseased persons by performing extensive testing and quarantine of suspects and contacts besides restricting travel, maintaining the norms of physical distancing and adopting proper hygiene and sanitization. The preferred first step to implement these measures for controlling COVID-19 by most countries was a Lockdown. India went into lockdown from 24th March 2020 as per government directive, which has subsequently been extended

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in multiple phases and has crossed Day 96 at the time of writing this report.⁷

Initial reports from China by Liang et al.⁸ suggested that patients with cancer were more susceptible to COVID-19 infection because of their immunosuppressed state. Additionally, they showed that patients with cancer had poorer outcomes from COVID-19 and hence called for more intensive handling of cancer patients during this pandemic. This drew the attention of oncologists all over the world to modify their practices and formulate specific guidelines to deal with the diagnosis, treatment and follow up of cancer patients, minimizing the associated risk of infection while providing optimum cancer care. This review article will provide insights on cancer care during COVID-19 pandemic.

EFFECTIVE CANCER CARE DURING COVID-19

Cancer patients are often immune-compromised and cancer treatment causes myelosuppression that leads to lowering of innate immunity. Other factors like advanced age, presence of comorbidities, malnutrition, debilitating surgeries and supportive medications like steroids also affect the immune response, putting patients at increased risk of COVID-19 related morbidity and mortality. Researchers from the COVID-19 and Cancer Consortium (CCC19) published data on 928 cancer patients with confirmed coronavirus infection from US, Canada and Spain and found 13% incidence of all-cause mortality within 30 days of diagnosis. Risk of death was higher among elderly, males, smokers, those with multiple co-morbidities and in patients on active cancer treatment with Eastern Cooperative Oncology Group (ECOG) performance status 2 or higher. They also found that treatment with hydroxychloroquine and azithromycin for COVID-19 had an increased risk of causing mortality in cancer patients.⁹ The other group from the University of Birmingham and the University of Oxford, UK, observed 800 patients enrolled in the UK Coronavirus Cancer Monitoring Project.¹⁰ Risk of death was significantly associated with patient's age, male sex and presence of comorbidities like hypertension and cardiovascular disease. However, unlike the CCC19 study, they observed that COVID-19 positive cancer patients on active treatment with chemotherapy, immunotherapy, hormonal therapy, targeted therapies or radiotherapy did not have the additional risk of death compared with those who did not receive those therapies. The investigators of this study from the UK concluded that withholding effective cancer treatments from many cancer patients during the pandemic ran a very real risk of increasing cancer morbidity and mortality, perhaps much more than COVID-19 itself.

Thus in this backdrop of competing risk of death and complications from untreated cancer versus COVID-19 infection in the immune-compromised host with cancer, delivering cancer care had become a herculean task. Implementation of lockdowns globally has made access to healthcare facilities by cancer patients even more challenging,

especially in developing countries like India because of cancellations of outpatient visits, delays in routine cancer screening,¹¹ surgery postponements or cancellations. However, it is a well-known fact that delaying cancer diagnosis and treatment adversely affects the prognosis and outcome and is not acceptable under any given circumstances.¹¹

There is no “one size fits all” approach, conceptual framework for balancing cancer risk versus infection risk and practical approaches for managing cancer patients during the pandemic are presented below.

General care for outpatients

The American Society for Clinical Oncology (ASCO) suggests the following guidelines.¹² All patients with cancer should be informed regarding the symptoms of COVID-19 and trained to maintain proper hygiene and avoid crowds and should be urged to wear a cloth face cover. Clinic visit that can be postponed without risk to the patient should be postponed. Pre-screening via telephone calls or digital platform for COVID-19 symptoms and exposure should be done before in-person clinic visits. Screening clinics should be developed to allow for patients with symptoms to be evaluated and tested.

CANCER SCREENING, DIAGNOSIS AND STAGING

There are concern about a halt in national cancer screening program during the pandemic and the potential long term detrimental impact of delays inpatient,^{11,13-15} population and health care system responses to suspected cancer symptoms. ASCO guidelines recommend postponing cancer screening procedures that require clinic/center visits. However, clinicians should follow guidelines specific to their region. It is reasonable to limit the staging procedure and pre-treatment evaluation only to those that are most necessary to inform the development of the initial care plan.

SURGERY

Various agencies have put forward there consensus statement for surgical management of cancer patient during the pandemic. Salient points of these recommendations are; surgery with shorter hospital stay and lower complication rates should be prioritized. Complicated reconstructive surgeries should be avoided. Surgery should be performed in patients who have finished their neo-adjuvant treatment. Surgery should be deferred in certain cases having a low risk of early relapse. Resection of primary tumour should be postponed in metastatic settings. Palliative surgeries should be postponed, except for life-threatening complications such as respiratory difficulty mandating tracheostomy or in cases with severe bleeding, or when delaying treatment will have negative consequences for patient's quality of life.^{16,17}

RADIOTHERAPY

Patients receiving radiotherapy with curative intent for rapidly progressive tumour should reasonably proceed with the therapy, as the risk of delaying the treatment may

outweigh the risk of COVID-19 exposure and infection.¹⁸ where available, alternative hypo-fractionated regimens should be offered e.g. short course neoadjuvant radiotherapy for rectal cancer, FAST/FAST forward-protocol for adjuvant radiotherapy in breast cancer. Radiotherapy for symptom control and in patients with low-risk progression or recurrence should be delayed or adjusted.¹⁹ patients actively undergoing radiotherapy with established treatment plans, the decision to continue requires careful consideration of; indications, dose already delivered and risk and benefits. Site-specific guidelines by American Society for Radiation Oncology (ASTRO), European Society for Radiotherapy and Oncology (ESTRO) and other global radiation oncology response groups can be considered with suitable adaptations fulfilling the local/regional guidelines.^{20,21}

CHEMOTHERAPY

There is no direct evidence to support changing or withholding chemotherapy or immunotherapy in patients with cancer who do not have COVID-19.²² ASCO recommends that clinical decisions should be individualized and consider factors such as the durability of cancer, the risk of cancer recurrence with treatment delay, modification or interruption, the number of chemotherapy cycles already complete and patient's tolerance of treatment. In general, adjuvant chemotherapy with curative intent should likely proceed, but shorter treatment duration should be considered wherever feasible. It is advisable to avoid bone marrow transplant procedures as far as possible. For patients receiving palliative therapy for metastatic disease, the decision to continue requires careful consideration of; indications, response and risk/benefits of continued treatment. Oral chemotherapy drugs or home infusion of chemotherapy drugs may be an option for some, but require coordination from the oncology team to ensure that patient is taking their treatment correctly. Lymphopenia seems to be a specific risk factor for adverse outcomes from COVID-19 and other coronaviruses hence critical re-evaluation of the need for drugs that inhibit B- cells,²³⁻²⁷ such as anti-CD-20 monoclonal antibodies, during the pandemic.

SUPPORTIVE CARE

ASCO has not recommended prophylactic use on antiviral therapy for COVID-19. Blood transfusion in patients can be given as per usual practice guidelines. For patients who are febrile and likely to be neutropenic based on the timing of their cancer treatment, it is reasonable to start empirical antibiotics if the patient seems stable. Although myeloid growth support is typically administered for those at high risk of febrile neutropenia, it may be reasonable for patients with a lower level of expected risk at the present situation.

RECENT TRENDS AND EMERGING RESEARCH

Remdesivir- a nucleotide analogue prodrug that inhibits viral RNA polymerase, has been found effective in reducing time to recovery in hospitalized patients with COVID-19 in US.²⁸ similarly, Favipiravir (FabiFlu) is approved to treat mild to moderate COVID symptoms.²⁹ most recently,

RECOVERY trial conducted by NHS in UK, showed that low-cost Dexamethasone reduced death from COVID-19 in one-third of the hospitalized patients,³⁰ with the highest benefit seen amongst those requiring assisted ventilation at admission. Based on the results, the NIH COVID-19 Treatment Guidelines Panel has recommended using dexamethasone (6 milligrams per day for up to 10 days) in patients of COVID-19 who are mechanically ventilated and/or require supplemental oxygen therapy.³¹

BBCI EXPERIENCE

Our institute is a regional cancer centre catering the cancer patients of the entire North East India. We used telemedicine extensively to reach out to our patients during the lockdown, Patients were educated about COVID 19 preparedness and appropriate advice was given to patients not on active treatment or on follow up and asymptomatic. However, newly registered patients, patients undergoing treatment and those with symptoms were attended and managed as per the protocols designed by COVID Task Force of our hospital. Prepared guidelines by the task force are based on international recommendations with suitable adaptations to meet regional needs. The directive of the Ministry of Health and Family Welfare, India on preventive measures to contain the spread of COVID-19 in hospitals was strictly followed during all stages of patient care in our hospital.³²

Till now we have encountered 4 positive cases of COVID-19 among our patients and 1 among the health workers, yet our treatment services have continued without interruption as we adopt the norms of Personal Protection and Facility Sanitization strictly which eliminates the risk of spread of Coronavirus in the hospital.

CONCLUSION

Providing timely and optimum cancer-directed treatment during the times of Coronavirus pandemic has been a massive challenge to oncologists and cancer centres worldwide. Cancer patients with COVID-19 infection are at increased risk of morbidity and mortality. Although there are limitations in resources and challenges in delivering optimum healthcare, cancer patients should be evaluated on a case to case basis and treatment should not be delayed or denied. Priority must be given to cancer patients on active curative treatment and those at lower risk of developing morbidity and mortality from COVID-19.

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REVIEW PAPER

Evolution of medical education in India: some miles travelled, many miles to go

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ABSTRACT

The earliest known stream of medicine emerged out of magico-religious sources, and knowledge was imparted through a gurukul system within ashrams. With the advent of colonialism, the first steps towards science-based western medicine were taken. Undoubtedly, post-independence, with the influence of western ideas, several advances have been made towards a seemingly modern medical education model. Yet, a tendency to blindly emulate admission and teaching models from other socio-cultural contexts has caused some deep loopholes in the Indian medical education model. While on the one hand privatization of medical education has rapidly shifted the focus from quality education to profit-oriented business expansions; on the other, an obsession with statistical success has diluted the need for meaningful teaching and learning. To add to it, even regulatory practices such as MCI inspections are carried out as mechanical exercises which fail to ensure any actual qualitative checks on medical institutions. The objective of this piece is to outline the most glaring loopholes of the modern-day Indian medical education system, and emphasize the need for competency-based, skill-oriented teaching and learning to ensure that the future of healthcare is not defined by mere commercial and statistical success.

Keywords: modern medicine, privatization of medicine, medical education.

VEDIC GURUKULS TO MODERN ALLOPATHY

From its emergence in the Vedic Ages (1500-600 BCE) as a magico-religious practice, medicine has trodden a long, convoluted path to reach its present formal, institutionalized, educational form. Ayurveda evolved as one of the earliest offshoots of traditional medicine which eventually transformed into a highly systematic science, both taught and practised. Even while knowledge was being imparted formally, in the initial years, it was taught under the Gurukul system in ashrams and on caste-lines.¹ The Charaka Samhita asserted that it is

training, not birth that makes a vaidya. Contemporaneously, other streams of medicine like Unani also developed under the influence of Arabic and Chinese traditions. The modern allopathic branch of medicine, however, developed once colonial rulers like the Portuguese and British came to India from the 16th century onwards.²

The colonial influence made an interesting cocktail of observational eastern traditional medicine and science-based western medicine. Initially, the practice of western medicine was largely confined to their military personnel. In 1822, the Native Medical Institution was established in Calcutta to provide medical education to Indians. In 1826, an Indian Medical School was started in South Bombay to teach western medicine but survived only six years. The Calcutta Medical College was established in 1835 to train Indian students “in strict accordance with the model adopted in Europe through the medium of English language.” Successful candidates were called native doctors and allowed to enter public service with initial pay of Rs.30 per month.²

Inevitably, a clash of culture emerged between traditional medicine and western medicine with the introduction of modern medicine by the British. While western medicine was accorded the status of ‘official medicine’, the colonial state turned discriminatory and hostile toward other systems. The silver lining of this clash despite significant socio-cultural consequences was a paradigm shift in the field of Indian medicine evidenced by the initiation of a public health system, vaccination, importance of vital statistics, epidemiology and research on some dreaded diseases like plague, malaria, tuberculosis, leprosy etc.²

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MODERN MEDICAL EDUCATION IN POST-INDEPENDENCE INDIA: PRELIMINARY LOOPHOLES

By 1947, 19 allopathic medical colleges were established. Post-independence, a plethora of new challenges emerged – there was a sudden qualitative decline in medical education, curriculums were found to be unsuited to the Indian context and a defective student selection process prevented the optimal workforce creation by medical institutions. Even after seven decades of independence, some of these hindrances remain. Today, India has around 542 medical colleges with 64 standalone post-graduate institutions. Approximately, 78348 undergraduate country-wide seats are available with a comparably increasing pool of postgraduate and other super speciality course seats. But the question is, is this sufficient? Given India's population statistics, it is quite insufficient. At present, India's population is around 1030 million and the incidence of doctor/population ratio now is stated to be 1:1700 with a desirable target of 1:1000, estimated to be achieved by 2031. It is also estimated that there will still be a shortage of 1 million doctors by the time India achieves the said target. Health indicators like Maternal Mortality Rate (MMR) and Infant Mortality Rate (IMR) are still far behind the desired goal. After the introduction of the National Rural Health Mission in 2013, there has been a marginal improvement in the state of affairs, yet drawbacks directly related to human resource availability continue to exist. The Bajaj Committee Report prepared in 1986 recommended the establishment of an Educational Commission of Health Sciences and simultaneously noted that most faculty at medical education institutions while being adept in their clinical specialities, lacked capacity as educators.³ Those states which followed these recommendations have eventually demonstrated better health indicators.

Another phenomenon in recent times in the medical education sector is an unprecedented boom in private medical colleges. Undeniably, the mushrooming of private institutions is a consequence of the government's apathy in the health education sector and the inability to provide both adequate number of seats as well as infrastructural avenues to medical students. With the privatization of the medical education sector, significant power has landed in the hands of influential politicians and businessmen, who in the guise of promoting medical education, are running these educational establishments as business houses. Besides, while educational avenues have been statistically enhanced due to these private establishments, issues of shortage of qualified faculty, the danger of imposter faculty, lack of transparency in fee etc. continue to remain unaddressed.⁴ In the present climate of cutthroat competition, a teacher-student ratio where more tutor attention is available to students is the need of the hour to ensure meaningful learning during apprenticeships.

BLIND EMULATIONS: TRACING THE DECLINE OF MEDICAL EDUCATION IN INDIA

Producing unskilled, semiskilled doctors and allowing them to treat a diverse population with no infrastructure is counter-productive; even, self-defeating. There is a huge disparity of medical training both at the regional and national level. Both government and private institutions have their limitations.

Western models of corporate hospitals and medical education institutions are being blindly adopted, without taking into account the populational angles specific to the Indian context. Corporate hospitals are also training postgraduates keeping their interests ahead. Many a time ad hoc decision, political considerations, self-interests, corruptions, inefficiency in implementations seem to be some of the reasons which cripple the system. The functioning of new AIIMS-like institutions can be considered as a glaring example of policy paralysis in tertiary care as also mentioned by the concerned Parliamentary Standing Committee.⁵

In this decade, medical education has become one of the most sought-after education streams in India. Approximately 16 lakh students are likely to appear in the NEET examination in 2020, of which only around 75000 students will qualify for undergraduate seats. Likewise, 89549 students qualified in the PG NEET out of 160888 candidates who appeared. They will be applying for around 31000 seats. Medical education is a career choice of preference for many reasons - it is considered to be a relatively stable profession with high social acceptance, while earnings are moderate initially, they can be eventually rewarding; family-owned healthcare establishments prefer continuity through generations; and finally, many opt-in with an idealistic notion of pursuing 'a noble profession', although the commercialization of healthcare in recent times has arguably eroded this nobleness.

It is difficult to say from which point the quality of medical education declined. One is definitely from the year 2013 when a common entrance examination was mooted. At the outset, this test is a wholly memory-based test where aspirants are screened based on multiple-choice questions. The deciding factor in such a scenario is not necessarily actual academic prowess, but simply the ability to memorize and retain large amounts of information. It does not test aptitude, problem-solving ability and skilful clinical performances etc.

Similar problems have crept into post-graduate selections too. Immediately following their undergraduate degrees, interns are focused on preparing for post-graduate entrance examinations. This tendency causes an inevitable compromise of their learning during the training period leading to long-term qualitative compromises. Private coaching institutes have established a dense country-wide network and preparation for entrance examinations has become a trade in itself.

Earlier, in medical colleges, subjects were taught as separate entities without any cross-subject integration. Inevitably, this led to unnecessary confusion, repetitions and a drain of time and energy. Since 2018, this disjointed approach has been partially replaced with a competency-based approach. It remains to be seen how this new approach will be implemented. At present, medical education in India is largely based on unrealistic rhetoric.⁶ A need-based curriculum, which takes into account the patterns of illnesses and diseases in the Indian context, is long overdue and needs to be introduced in place of a subject-oriented monotonous model of teaching currently in practice. Due to the lack of adequate infrastructure, students are unable to obtain any hands-on practice of their academic learnings. While it would be unrealistic to suggest a complete overhaul of the existing

system, a well-thought-out, time-bound and purposefully implemented way forward is needed to be worked out on an urgent basis. Some steps in the right direction have already been taken. For instance, AETCOM (Attitude, Ethics and Communication) modules have been introduced which emphasize the significance of a right attitude, ethics and communication skills in the medical profession. In addition to this, it may also be helpful to include behavioural sciences and managerial skills to ensure a more holistic medical education. The focus should be on the operational and practical part of accumulated knowledge. The core curriculum of medical education should be segregated based on practical relevance into three broad categories - 'must learns', 'practically useful to learns' and 'academically good to learns'. Another problem that cripples medical education is the medical teachers' selection process. The Medical Council of India (MCI), now the National Medical Commission (NMC), which is replaced by the Board of Governors has only undergone a nomenclatural change while its functions remaining the same. It sets the regulations for the selection of medical teachers. No measures are set for quality assessments. Publications are made a mandatory requirement in recruitment processes; however, no avenues are in place to ensure skill-building for meaningful academic writing. In government medical colleges, frequent transfers made largely on political considerations clubbed with inadequate infrastructures make research secondary. In their attempt to establish new medical colleges, the same group of teachers are transferred from one college to another overnight, leading to an illusion of expansion of medical education establishments with nothing more than a massive quality compromise in reality. It is rather surprising that the NMC itself does not maintain records of faculties of different medical colleges and is ill-equipped to detect artificial manpower overlaps. Even simply monitoring the number of faculty (which is itself often artificially built to serve MCI inspections) is grossly insufficient, the ability to impart quality teaching needs to be measured. Since the introduction of the Curriculum Implementation Support Program (CISP), some movement in the right direction has been seen with an emphasis on problem-based learning, evidence-based medicine, CME and use of technology in classroom teaching. Another ironical practice is the inspection by MCI inspectors who belong to the same pool of government medical teachers with their limitations. In the absence of any specific training, it is almost as if they momentarily attain some divine superiority and excellence with the ability to examine and assess the same loopholes which they often fail to identify in their home institutions. A mindlessly strict approach, without consideration for the various practical circumstances within which an institution operates, can often destroy an institution at its threshold along with the future of enrolled students. Thus, instead of an ad-hoc assessment by professionals not necessarily equipped with any special training, a meticulous, time-consuming, fact-finding, remedial exercise should be carried out by trained inspectors with the facilitation of growth

of institutions inspected as the primary goal. In my professional career, I have frequently been engaged in the inspection of some medical colleges and seen colleges lacking clinical materials and faculties still obtain materials in time for inspection with the aid of informal advice routes. Such an approach fails not only a particular institution but the entire medical education sector since it becomes impossible to assess the true potentiality of inspected institutions. While this assertion may be difficult to prove, it is an open secret of the medical education sector.

CONCLUSION: A WAY FORWARD

Undoubtedly several miles have been travelled in the Indian medical education sector towards making the same 'progressive'. Yet, the system continues to be blinded by its obsession to not only mimic western models but also to create mere statistical success. Many miles remain to be travelled to ensure substantive and sustainable reforms which lead to a better screening process of medical aspirants, a thorough and hands-on teaching model in undergraduate and postgraduate studies and finally a qualified and widespread network of committed medical professionals at institutions of quality. Measures have to be initiated both at a regulatory level by the NMC as well as at the level of individual teachers and institutions, with complete commitment at both levels to academic excellence. Most importantly, the prevalent tendency of pandering to the number game at the cost of complete dilution of the nobleness of the medical profession has to be done away with, with a sense of both personal and institutional urgency.

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Contribution of the author: I declare that this work was done by the author named in this article and all liabilities about claims relating to the content of this article will be borne by the author.

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REVIEW PAPER

Anecdotal use of convalescent plasma: an option in severe COVID-19 patients

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ABSTRACT

Originating from Wuhan, China the Coronavirus Disease (COVID-19) has now achieved proportions of a massive pandemic. The threat posed by the disease has mutilated health systems across the world. Time and again, researchers have strived to discover a definite cure but with no success so far. The time required to propound a vaccine might take a year or more. The healthcare delivery system has employed antivirals, supportive care, and isolation strategies over the months. In this dire scenario, convalescent plasma therapy (CPT) could be a harbinger of hope, given its success in the previous influenza-like illnesses. Though this disease has salient features quite different from classical influenza, yet the symptoms are roughly similar. Plasma therapy experiments conducted throughout different countries yielded variable results, yet not negative. Patient factors, the severity of the disease, and the strain of the virus could have a drastic effect in the course of therapy. India, too, has conducted some successful passive antibody transfusions, but the wide-scale result is not precise. The potential merits can be obscure presently. We have to consider the willingness of the donors at the same time. CPT has emerged to be feasible and might prove to be efficacious in the long run.

Keywords: Plasma transfusion; passive immunity; passive antibody transfer; SARS-CoV-2; pandemic.

INTRODUCTION

Over the last few months, a lot has changed across the globe. Pneumonia of unknown cause detected in Wuhan, China was first reported to the WHO country office in China on 31st December 2019,¹ which spread rapidly, with cases now affecting 213 countries and territories around the world and 2 international conveyances.²

Strangely, the impact of the disease is different in different countries. These differences are attributed to differences in cultural norms, mitigation efforts, and health infrastructure.³

Researchers from China's Centre for Disease Control and Prevention (CDCP) describe the clinical findings on more than 72,000 COVID-19 cases reported in mainland China, which reveal a case-fatality rate of 2.3% and suggest most cases are mild, but the disease hits the elderly the hardest.⁴

A total of 81% of cases in the JAMA study were classified as mild, meaning they did not result in pneumonia or resulted in only mild pneumonia, 14% of cases were severe (with difficulty in breathing) and 5% were critical (in respiratory failure, septic shock, and/or multiple organ dysfunction or failure).⁴

The mortality rate of COVID-19 is varied country to country but in India, it is 2.82% among the lowest in the world compared to a global mortality rate of 6.13% on June 4, 2020.⁵

Therapeutic options including antimalarials, antivirals, and vaccines are under study. Meanwhile, the current pandemic has called attention over old therapeutic tools to treat infectious diseases.⁶

Recently much has been talked about the CP in the line of

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treatment of COVID-19 patients around the world recently. Therefore, the authors aim through this short review paper, to explore the feasibility of CP transfusion to rescue severe COVID-19 patients in the current situation.

CONVALESCENT PLASMA (CP) AND ITS RELATED ISSUES

CP refers to the plasma separated from the blood of patients who have recovered from a particular disease. It consists of immunoglobulin IgG or IgM that has the potential to act against the antigens in new active patients. The transfusion of this plasma to an active patient helps in neutralizing the pathogenic microorganism, thus, enabling the patient to mount an immune response against the said pathogen. However, the implementation of a convalescent plasma transfusion program might need comprehensive planning. As we consider its use in the battle against this new strain of coronavirus, it is prudent to review the knowledge from past experiences. There is a lack of evidence for the treatment of COVID-19 and vaccines. Therefore, Classical and historical interventions have re-

emerged as options for the control of the disease.⁷

Several pieces of research are still on the run. The world is dealing with a new virus, but no vaccine has developed that could provide a cure. The characteristics of the virus are also not determined. There are wide speculations about the course it would follow.

CP constitutes the first option in the current situation since it has been successfully used in other coronaviruses outbreaks.⁶ Therefore, it may be considered as an alternative to the treatment of COVID-19 until an efficient vaccine or drug is universally approved.

Timeline of COVID-19

Before substantial investigations into management could be underway, WHO had to declare the outbreak of pneumonia-like illness of unknown cause detected in Wuhan on 31st December 2019, as a Public Health Emergency of International Concern on the 30th of January 2020. Currently tagged as a global pandemic, it has encompassed all boundaries

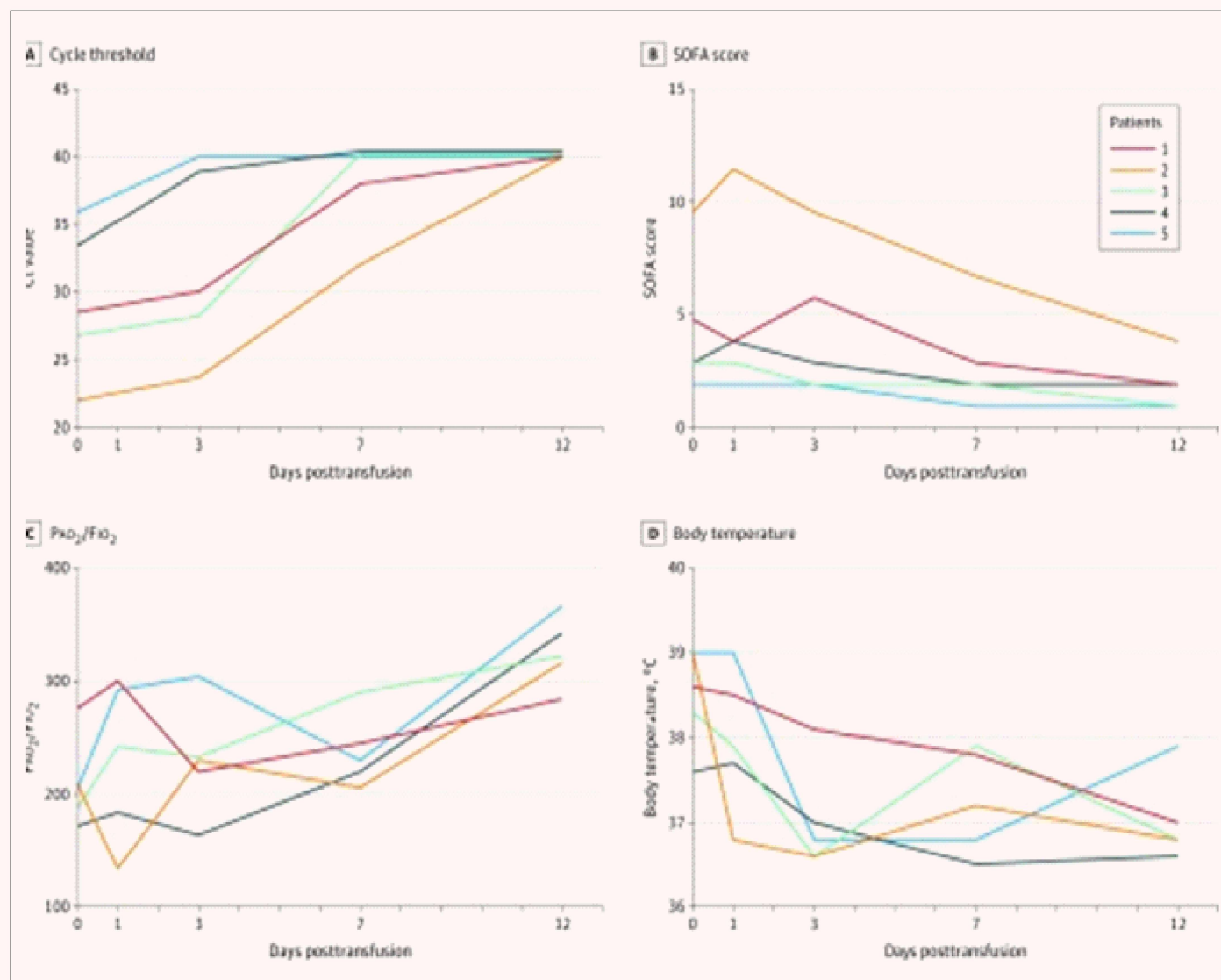


Figure 1 Post-transfusion changes¹⁰

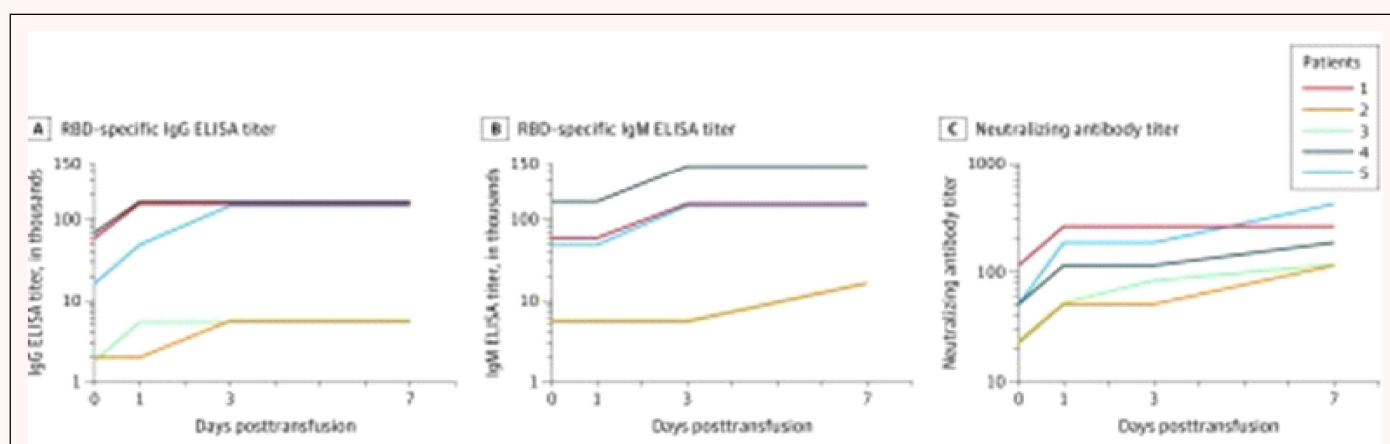


Figure 2 Changes in antibody titers¹⁰

with 10 million reported cases and 500 thousand deaths.⁸

Health facilities worldwide are facing the worst possible nightmare with huge patient inflow and still no well-determined cure. The virus was identified as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a member of the family of coronaviruses, which were known to cause previous epidemics like SARS-Cov-1 and MERS-CoV. This new disease was named COVID-19 (coronavirus disease 2019) on 11th February 2020.⁸

Trials across the world

Medical research institutes have taken up clinical trials to test many drugs and therapies. Researchers are taking into consideration the proposal of using CPT. Passive immunization for the prevention and treatment of human infectious diseases has been traced back to the 20th century. CP has been a therapeutic modality employed for over a hundred years for various infectious pathogens. The recent Ebola virus outbreak, which had a mortality rate of 8% (as against 2% of COVID-19), had shown the benefits of using CP or convalescent whole blood.⁹

The infectious disease department at Third People's Hospital in Shenzhen, China, took up a study from January 20, 2020, to March 25, 2020. Five COVID-19 positive patients were administered to CP. These patients were in the age range of 36-65 years (2 women). They were receiving mechanical ventilation at the time of treatment, and all had received antiviral drugs along with methylprednisolone. Following plasma transfusion, body temperature normalized within three days in 4 of 5 patients, the **Sequential Organ Failure Assessment** (SOFA) score decreased, and Pao₂/Fio₂ increased within 12 days (range, 172-276 before and 284-366 after).¹⁰

SOFA score helps us track a patient's status during their Intensive Care Unit stay to determine to what extent the person's organs are functioning or whether the organs are deteriorating into failure. Furthermore, even viral loads decreased and became negative within 12 days after the transfusion, and SARS-CoV-2-specific ELISA and neutralizing antibody titers increased following the transfusion

(range, 40-60 before and 80-320 on day 7). Four patients with Acute respiratory distress syndrome (ARDS) recovered at 12 days after transfusion, and three patients no longer required mechanical ventilation within two weeks. Of the five patients, three got discharged from the hospital (length of stay: 53, 51, and 55 days), and two are in stable condition at 37 days after transfusion¹⁰ (**Figure 1** and **Figure 2**).

Trials in India

Following these studies published across the world, India as well took up CPT trials. India's Central Drugs Standard Control Organisation (CDSCO) permitted the Indian Council of Medical Research (ICMR) to conduct a clinical trial of CP for the treatment of COVID-19.¹¹ ICMR also submitted a list of institutes that have shown an interest in the proposed trial. This trial was conducted as an open-label, randomized, controlled Phase II to evaluate the safety and efficacy of convalescent plasma in patients with moderate COVID-19 infection.¹²

On April 26th, Max Hospital, Delhi announced that an active case showed "progressive improvement" with CPT. In another very recent advancement, at Blood Bank Sassoon Gov Hospital at Pune, the first CPT has been performed successfully, as announced on 22nd May. The patient was given plasma for two continuous days on 10th and 11th May.¹³ These achievements play a monumental role in defining the behaviour of this virus. However, this calls for tremendous foresight and sustainability goals when it comes to using CPT on a large scale for a developing country like India grappling with more than 530 thousand cases recorded presently.

Standard procedures lay down that the convalescent donors must undergo a stipulated pre-donation assessment to ensure compliance with current regulations regarding plasma donation. Currently, convalescent donors between 18 and 65 years are considered subjects. They should be without infectious symptomatology and test a negative for COVID-19 after 14 days of recovery. These tests must be repeated 48 hours later and at the moment of donation. Apheresis is the recommended procedure to obtain plasma. This procedure allows selective collection of plasma, based on continuous

centrifugation of blood from a donor. The efficiency of this technique is around 400–800 ml from a single apheresis donation. This amount of plasma could be stored in units of 200 or 250 ml, and frozen within 24 hours of collection, for use in further transfusions. There is not a standard transfusion dose of CP. In different studies for coronaviruses, the administration of CP ranges between 200 and 500 ml in single or double scheme dosages.¹⁴

In addition, donor eligibility criteria for whole blood and plasmapheresis donation will be followed in accordance to the Drugs & Cosmetics Act 1940 and rules 1945 therein (as amended till March 2020).¹⁵

Currently, the recommendation is to administer 3 ml/kg per dose in two days. This strategy facilitates the distribution of plasma units (250 ml per unit) and provides a standard option of delivery in public health strategies. Interestingly, it is supposed that plasma from healthy donors provides immunomodulatory effects *via* the infusion of anti-inflammatory cytokines and antibodies that blockade complement, inflammatory cytokines, and autoantibodies.¹⁶

These factors may influence the immunomodulatory effect of CP in patients with COVID-19. This is because, during apheresis, in addition to neutralizing antibodies, other proteins such as anti-inflammatory cytokines, clotting factors, natural antibodies, defensins, pentraxins, and other undefined proteins are obtained from donors. In this sense, transfusion of CP to infected patients may provide further benefits such as immunomodulation *via* amelioration of severe inflammatory response.¹⁷

Pro and cons

The pros would include possible clinical efficacy, immediate availability from a large donor pool, relative ease of procuring plasma through current approved methods, and potential cost advantages over some of the more experimental antivirals.¹⁸ Additionally, CP may also offer prophylactic benefits, which could keep our healthcare workers on the frontlines healthy as well as prevent self-quarantine after exposure, which risks decreasing an already overstretched workforce.¹⁹ Clinically, some investigators have attempted to assess the prophylactic potential of convalescent plasma.²⁰

The cons also include basic administrative and logistical barriers of identifying, consenting, collecting, and testing donors. Finding donors with the robust humoral response could be a hurdle as well, as not all recovered patients have detectable antibodies in the convalescent stage.^{21,22} Besides, the antibodies being highly specific, may not be effective against mutant forms of the viruses. Individual variations have to be covered simultaneously.⁸

Additionally, the current lack of widely available and validated SARS-CoV-2 antibody assays, particularly assays detecting neutralizing antibodies, may hamper identification of ideal donors. Concentrating for neutralizing activity may also mitigate potential viral antibody-dependent enhancement (ADE), a process in which plasma antibodies exacerbate

disease by enhancing viral cell entry and viral replication by various mechanisms, some of which have been described in MERS infectious model.^{23,24} Theoretically, ADE could exacerbate COVID-19 infection in patients who receive CP from donors who were not tested for SARS-CoV-2 specific neutralizing antibodies. Moreover, the administration of passive antibodies can suppress the recipient's humoral immune system from generating pathogen-specific antibodies thereby leaving an individual susceptible to reinfection.²⁵

Pathogen reduction could improve the safety profile of CP. One study found that psoralen treatment did not substantially reduce the titers of anti-EBOV specific antibodies or their neutralizing effect.²⁶ These findings are promising as they indicate that CP can be safely modified to reduce infectious risk without disrupting possible efficacy. Finally, there are non-infectious hazards of transfusion²⁷ which include transfusion reactions such as transfusion-related acute lung injury, transfusion-associated dyspnea, transfusion circulatory overload, and serve allergic reactions with associated bronchospasm, all of which could worsen respiratory disease in COVID-19 patients, especially those who are already on supplemental oxygen and/or intubated. Therefore, much more work is needed on CP before drawing definitive conclusions.

Ethical consideration

The WHO Guidelines on drawing blood: best practices in phlebotomy may provide a useful source of information.²⁸ Informed consent should be obtained for the donation of convalescent whole blood or plasma. The informed consent for transfusion of CP is to be obtained from the patient or the family members as well.¹⁵

CONCLUSION

The questions which might emerge here is, how well the general population would receive this treatment modality and what recovery rates it might anchor at large. Questions that still might remain unanswered include, whether we will find an established cure or do we have to resort to other strategies. It may take an enormous length of time to formulate a vaccine. Thus, in these times of crisis, plasma therapy can open new doors to recovery, survival strategies and emerge as a beacon of hope. What is required is extensive research and an indomitable spirit. "Medicine is a science of uncertainty and an art of probability" – as William Osler has said.

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REVIEW PAPER

Macro-micro linkages and its effect on global public health in regards to COVID-19 pandemic

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ABSTRACT

COVID-19 pandemic has changed our lives in a significant way, this is one of the biggest health crises that the world has ever seen, life has come to a standstill all over the world. Hundreds of thousands of people have lost their lives—this is not only a health crisis but it is an economic, social and political crisis as well. Merely looking it through the lenses of health will not serve the purpose, interdisciplinary framework must be adopted to understand this crisis more substantively. The objective of this review paper is to understand how the neoliberal growth model has increased the possibility of transmission of zoonotic diseases in humans and to why lessons learnt from the SARS pandemic didn't lead towards necessary changes in institutional and community level. To answer these questions, there is a need to review the situations created by SARS in 2003. Compared to 2003, things have changed drastically, there has been huge growth seen in the global economy and the world is far more interconnected. This interconnectedness has facilitated the spread of coronavirus, but the SARS pandemic should have served as a warning. Then the WHO was highly praised for its swift reaction in preventing the spread of the virus, whereas now it has come under global scrutiny. This pandemic should be looked through macro-micro linkages to understand its high level of spread in the society. Failures at the global, institutional and the community level have culminated in creating one of the biggest crises that humanity has ever seen.

Keywords: Interdisciplinary; substantive; transmission; zoonotic.

THE COVID-19 SITUATION

The COVID-19 pandemic has raised many questions.

Researches are still focused on understanding how the virus functions. Development of several vaccines are going on in a war footing, medical infrastructure has been ramped up by several countries. It is going to take a lot of time until the focus of the research works shifts towards the origin and spread of the virus. Although several countries like Australia and USA have demanded an independent inquiry into origins of the virus—it is not the priority, the focus is on 'containment' of the virus. China has threatened Australia with 'economic consequences' if it continues to demand an independent inquiry by restricting Chinese students and travelers, a huge source of income for Australia. China is the largest trading partner of Australia, it is not in the interest of Australia to disappoint China, it is interesting to understand the reasons behind Australia taking such a risky initiative. The study and practice of foreign policy neglected public health, and it was predominately a domestic concern.¹

Most of the countries are focusing on slowing down the spread of the virus—countries like New Zealand and Japan have succeeded in doing so, but it remains to be seen if these countries will face a second wave of the virus. At the time of such a global calamity—it is difficult to focus on other aspects,

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other than saving human lives. But if questions are not asked regarding the various aspects of the spread of SARS-CoV-2, it is only a matter of time when we will have to deal with a completely different ‘strain’ of coronavirus. Technology has helped us to determine the ‘genetic sequence’ of the virus, it has helped us to determine that this virus binds perfectly with the ACE2 ‘protein’ in human cells. Different strains of the virus have already been identified, it is only a matter of time, after which a solution to this ‘problem’ will be found. Virologists are pointing out that after some years this particular virus will lose its ‘potency’, it will then exist around us like any other ‘flu virus’.

CONNECTION WITH PAST EXPERIENCES

By the natural process of ‘herd immunity’ or with the help of technology, this ‘pandemic’ will come to an end. Although it is difficult to imagine the post-COVID-19 world, it is very important to analyze the mistakes that led to the spread of this disease to every corner of the earth. Merely investing in health infrastructure and technology will not help us prevent another similar situation in the future. Humanity faced a similar situation in 2003, during the SARS pandemic, the failure to properly address the issues raised by the researchers after the pandemic has brought us to this situation. The present situation is ‘strikingly’ similar to the SARS pandemic, there is a need to look into this situation by taking necessary inputs from previous researches on SARS pandemic. After over five months of denial, growing external pressure forced Chinese leaders into action.²

It is interesting to understand how the ‘growth model’ created by institutions like IMF and WTO in a world dominated by neoliberal ideas has increased the chances of the health crisis. Merely questioning globalization will not answer the question, if it has led toward the spread of the virus, global cooperation can also help in preventing it. In 1995 the WHO adopted Resolution 48.7 that started the process of revising the regulations to bring them up to date in terms of public health policy.³

The WHO is continuously suggesting the declaration of the ‘vaccine’ as a ‘global public good’ upon its arrival, this will ensure that it becomes available to each of the nations. Global cooperation is very much essential for the betterment of “global public health”, which is in the interest of all the nations. The field of global health in international relations is rapidly maturing.⁴ Recently, USA stopped its funding to the WHO, citing its incompetence and ‘probable’ arm-twisting by China. WHO has continuously praised China during the SARS pandemic as well as COVID-19 pandemic, tactically these praises can help in extracting information, especially from a country which has tight information controls.

NEO-LIBERAL GROWTH MODEL AND COVID

China’s economic growth allowed it to ramp up its ‘public-health infrastructure’, it was able to secure basic health services to each of its citizens. With a GDP of over 15 trillion dollars, it can afford to provide the best of medical treatment to its citizens. The COVID-19 pandemic showed that

economic power and health-infrastructure is not enough to fight a virus, experiences of countries like Italy and the USA proves this point. China was able to slow down the spread of the virus due to its harsh ‘coercion’ measures—it is only possible in a non-democratic country. Today, the concept of national security, and even the idea of national sovereignty, is being challenged by the spread of infectious disease.⁵ Italy had to adopt strict measures similar to China, and it did have an impact. So, it is seen that technology has failed us, investing in ‘health’ related technology in the future course of action will not serve many purposes. So, what should be done? How to address this kind of issues in the future? The best way to look into these questions is by revisiting the questions asked after SARS pandemic. Scholars of China’s foreign policy, are focused on China’s military capabilities and intentions and the security consequences of China’s economic rise. Non-military factors are rarely taken into account.⁶

It is a common belief that “prevention is better than cure”, therefore, it is very logical to not come into contact with zoonotic diseases, rather than focusing on technology to cure these. The countries with the best healthcare infrastructure are finding it difficult to prevent the thousands of deaths occurring daily. It is very plausible that a very different strain of coronavirus in future can wreck a similar ‘havoc’ even if a vaccine or cure is developed for the current strains of the virus. Therefore, there is a need to question the current ‘economic growth model’, relating to the development of health infrastructure.

To simplify, let’s take an example: The countries with higher levels of growth and GDP or the first world countries have far better health infrastructure than countries with lower income levels like the third world countries. It is because they can invest far more in ‘healthcare’ but the very economic growth model adopted by these countries has been responsible for creating a global health crisis.

RE-EMERGENCE OF ANTI-GLOBALIZATION DEBATE³

It can be argued that the virus didn’t originate in the first world countries, consensus exists that the virus originated from China. There have been many theories, the most common is that the virus originated from the ‘wet-markets’ in China. It is well known that the Chinese have the habit of killing wild-animals, those are considered a ‘delicacy’ in China. The ‘pangolin’ which is a rare species is regularly eaten in China, it is even smuggled; it is being said that the virus transmitted from bats to pangolins and then to humans. Although the virus has bat strains, the pangolin link is yet to be established. Another theory blames the virology lab in Wuhan for doing research that led to ‘development’ of highly efficient spike protein in the ‘coronavirus’, that binds effectively with human cells. Most of the virologists agree that the virus has natural origins, although the lab theory should not be denied until there is proper evidence. It is plausible to go with the natural origins of the virus if we look into the SARS pandemic. It had similar origins, the same

country was the ‘hotspot’ of the virus, the SARS pandemic resulted in globalization vs anti-globalization debate, it talked about new norms and strengthening of ‘state controls’. By late 1990, anti-globalization movements gradually gained enough strength to contest the value, policies and practices of globalism.⁷ But the world became much more globalized and interconnected than ever, the ‘retreat’ of the state continued. It is very natural that after this pandemic, there will be some drastic changes in these spheres, investment in healthcare is also going to increase. It is no use and even counterproductive to try and prevent the perils by reversing the process of globalization; the perils can only be contained by deeper globalization.⁸ The linkage of WHO-WTO might become a reality, which has been suggested by earlier researches. The world needs a robust process to adjudicate conflicts about economic/trade measures in global health emergencies.⁹ Even if all these steps are taken, it won’t be enough—there is a need to focus on macro-micro linkages through ‘interdisciplinary’ lenses. It is important to understand the bigger picture, the argument should be focused on the western countries. The model of development adopted by the western countries had a serious impact on the environment, due to heavy industrialization.

THE LINK BETWEEN ECONOMICS AND HEALTH

Concepts like ‘ecologism’ emerged in western countries, they began to rapidly de-industrialize themselves and sent their industries to third world countries like China. Availability of ‘cheap’ labour was not the only reason for de-industrialization, environmental concern was one of the core areas. The coming of many industries in China, ensured a very high growth rate for China, it became one of the biggest economies, second only to the USA, but China and the world had to pay a very heavy price for it. This was not a ‘non-zero-sum game’ or a win-win situation for all, the coming of various new industries in China increased human interaction with the wildlife. It is well known that the current model of development is detrimental to wildlife, it leads to various problems like ‘deforestation’, the most dangerous thing is that this has brought us ever closer to wildlife. Most of the western countries are threatening to call back their industries from China, Japan has provided 2.2 billion-dollar incentives to its industries to return. Other western nations are thinking to shift their industries to other third world countries like India. This should not be viewed as just an ‘economic punishment’ to China for failing to control the spread of the virus, but it has much deeper implications. China, perhaps like most countries, treats infectious disease as medical problems, requiring a medical response. This could explain why it took four and a half months after the first cases of SARS emerged in China before the Chinese authorities alerted the WHO.¹⁰ Even if these industries are shifted to other countries like India, the future might see India becoming ‘hotspot’ for future pandemics. Therefore, any decisions regarding attracting the ‘multinational companies’ to India must be taken after serious considerations about the environment. The genetic diversity

existing among zoonotic viruses in bats increases the possibility of variants crossing the species barrier and causing outbreaks of disease in human populations.¹¹ Otherwise, we might make a huge mistake in between an ongoing pandemic, that will set the stage for another global pandemic in the future. The researches should be more focused on preventing animal-human interaction, the proper emphasis should be put into ‘population control’. Reduction in population will surely decrease the burden on health infrastructure and the planet as a whole, already 1.5 ‘earth’ is required to sustain the current population. The growth of the population is a very big threat to humanity. The rapid spread of the virus has been due to the high density of human population.

IMPORTANCE OF COORDINATION

Therefore, questioning globalization and shortage of funds for health facilities might only answer a part of the problem, the analysis of this pandemic should be done on a much wider scale. The importance of global institutions and the countries at the macro-level and the interaction of the community with wildlife at micro-level should be looked at. Strengthening of health facilities is a must, it should be promoted at all levels of decision making. Further, rapid economic growth must be questioned, health and economic development should be taken together, the current model of development has resulted in numerous health hazards. The environmentalist, health professionals, economic advisors, lawyers, decision-makers, NGOs and the CSOs should all come together to plan the future course of action. The countries of the Global North must cooperate with countries of Global South because only safe and hygienic conditions for the people of these countries can ensure a world free of pandemics. The virus originated from China, but it still managed to travel to the USA, stopping all kinds of travel is not logical and will have a devastating impact on global economy and lives of the common people. Therefore, a practical solution to this problem must be found, which requires global level and community level coordination. Lessons from the SARS experience of China must be looked into. In terms of public policies on environmental protection and public healthcare, the government’s delinquency helped cause the SARS outbreak, environmental pollution also played a major part.¹²

It can be concluded that coronavirus pandemic is a result of extreme forms of development model. This type of development trickles down from the macro-level to the micro-level, affecting all sections of the society. Therefore, more emphasis should be put into determining the exact causes of global pandemics. Economic growth has huge implications for global public health, lessons from the SARS pandemic must have been incorporated in the neo-liberal growth model. Global cooperation and coordination between macro and micro-level institutes is a must to fight pandemics of the future. Society has to adopt changes to stay away from zoonotic diseases, emphasizing the need for questioning the current growth model.

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REVIEW PAPER

Saliva: potential role in the diagnosis of human coronavirus

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ABSTRACT

Saliva is a reservoir of the various biological marker and provides superiority over other biological fluids. Rapid and accurate diagnosis of SARS CoV-2 is essential to control the ongoing COVID-19 pandemic. Nasopharyngeal, oropharyngeal swab, bronchoalveolar lavage, sputum, urine, and blood are frequently tested sample but all these techniques are invasive and uncomfortable to the infected person. Therefore, the potential use of salivary sample can be taken into consideration as an alternative tool as it has various advantages over the current traditional methods. Salivary diagnostics also can be utilized as chair-side tests for various diseases soon through conscientious testing.

Keywords: SARS CoV-2; COVID-19; salivary biomarkers; diagnosis of viral infection.

INTRODUCTION

The emergence of coronavirus in December 2019, has caused a large global outbreak and is a major public health issue.¹ Coronaviruses are enveloped, single-stranded RNA viruses with high rates of mutation and recombination having the spike surface glycoprotein (S), a small envelope protein (E), matrix protein (M) and nucleocapsid protein (N).²

SARS-CoV-2, as it is commonly known, has been found to spread more rapidly than MERS-CoV with most common symptom being fever and cough.³ Bilateral lung involvement with ground-glass opacity is the most common finding of coronavirus disease (COVID-19) from computed tomography images of the chest,⁴ spread by human to human or direct contact and infection has estimated to have a mean incubation period of 6.4 days and basic reproduction number of 2.24-3.58.⁴

Efforts to control SARS-CoV-2 depend on accurate and rapid diagnostic testing. These tests must be sensitive to mild and asymptomatic infections to promote effective self-isolation and reduce transmission within high-risk groups, consistent to reliably monitor disease and aid clinical decisions.⁵

Nasopharyngeal or throat swabs are commonly used sampling method for viral load monitoring. Direct inspection of the patient's posterior pharynx and tonsils is recommended during throat swab collection. It can induce coughing and sneezing which generates aerosol and is a potential health hazard for health-care workers. Moreover, the collection of nasopharyngeal specimens is a relatively invasive and uncomfortable procedure even can induce bleeding. A patient's reluctance to provide a sample can account for the scarcity of time points in viral load studies of respiratory virus infections. Previous studies have shown high concordance between nasopharyngeal aspirate and saliva as specimens for laboratory diagnosis of respiratory viruses.³ The healthcare providers, doctors, nurses, and paramedic staff will be safe from the transmission of disease while using saliva as a specimen. Hence, this method of sampling is advantageous

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compared with the use of nasopharyngeal aspirates.⁶

This review paper explores the role of saliva in the diagnosis of COVID-19 and its related issues.

ROLE OF SALIVA

Saliva is an exocrine secretion of major and minor salivary gland comprising of approximately 99% water, variety of electrolytes, proteins represented by enzymes, immunoglobulins and another antimicrobial factor.⁷ With the emerging latest technologies saliva has been studied thoroughly as a potential diagnostic apparatus to become an alteration for other biological fluids such as serum or urine in disease diagnosis. They have disclosed large numbers of medically important salivary biomarkers for various disease conditions including cancer, autoimmune, viral, bacterial, cardiovascular, and metabolic diseases.⁸ Any alteration in the composition and quantity of saliva can help in the detection of various diseases.⁷

POSSIBLE DIRECT INVASIONS INTO ORAL TISSUES

SARS-CoV-2 can be presented in saliva through three different routes.^{7,9,10}

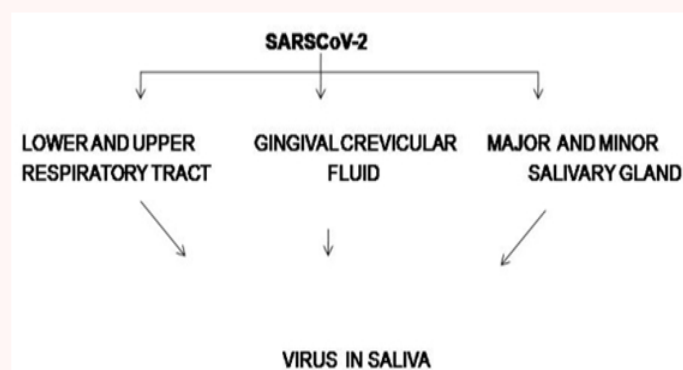


Figure 1 Routes of invasion of SARS-CoV-2 in saliva

INTERACTION BETWEEN HOST CELL IN ORAL CAVITY AND VIRUS

The entry of coronavirus into the host cell is a multi-step process using multiple distinct domains in the spike protein

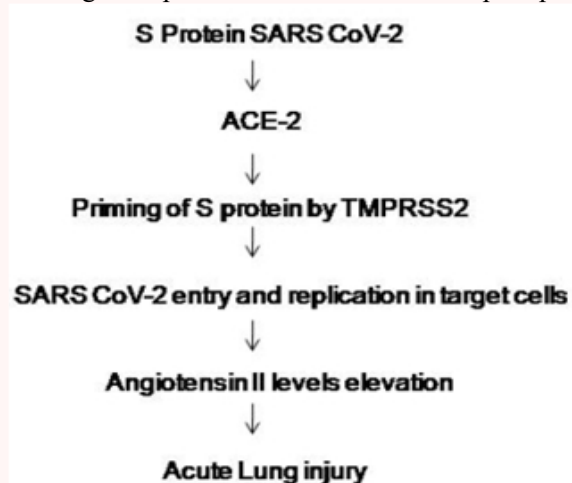


Figure 2 Relation of SARS-CoV-2 with ACE receptor¹²

that facilitates attachment of the virus to the surface of the cell, engagement of the receptor, processing of proteases and membrane fusion. The SARS-CoV-2 uses ACE2 as the receptor for viral entry and transmembrane protease serine 2 (TMPRSS2) for priming of the spike protein.^{2,11}

Expression of the enzyme furin on the tongue has been implicated in virus infection by cleaving viral envelope glycoproteins and enhancing infection with host cells.¹ Hyposalivation can disrupt the physical barrier of the oral and airway mucosal surfaces. This enhances viral colonization and adhesion. The decrease may also produce disturbances in the secretion of antimicrobial peptides and proteins. Considering the existence of various proteins with established antiviral characteristics in saliva may potentially obstruct virus replication especially SARS-CoV-2.⁹

SALIVA FOR DETECTION OF SARS CoV-2

RUCDR Infinite Biologic researchers at Rutgers University have successfully demonstrated saliva as a sample source for COVID-19 detection compared to nasopharyngeal or oropharyngeal swabs. SARS-CoV-2 invades the epithelial cell of rhesus macaques in salivary gland ducts. However, it should be noted that saliva specimen also contains secretion from the nasopharynx and lungs via the action of cilia.⁷ Viral load peaks can be detected early in salivary specimens at the onset of infection.¹ Studies have shown that some viral strain can be detected in saliva as long as 29 days after infection enhancing the disease detection.^{10,13} Dental/oral and other health professionals must always be diligent in protecting against the spread of infectious disease. Small droplets with a diameter of less than or equal to 60 μm can cause short-range transmission for individuals with distance less than one meter. In a desirable environment, small droplets are likely to fade away into droplet nuclei with a diameter of fewer than 10 μm . It then becomes capable of long-range aerosol transmission. For a susceptible host can enter the mouth, eyes, or be inhaled directly into the lungs thereby causing infection.^{7,9}

Antibodies against SARSCov-2 in saliva and its potential in diagnosis

Previous studies have shown the production of SARS-CoV-2 specific secretory immunoglobulin A (sIgA) in the saliva of animal models.¹⁴ Immune responses, including the production of SARS-CoV-specific serum immunoglobulin G (IgG) and secretory immunoglobulin A (sIgA), were determined in animal mucosal secretions and tissues.¹⁵ Saliva-based antibody tests are there to detect several viruses and the presence of immunoglobulin can help by the rapid diagnosis of COVID-19.

Methods of collection of saliva

There are many saliva collection devices available in the market for safe and sterile collection without compromising the quality and quantity. Self-collection of saliva can also be done and usually, an early morning saliva sample is preferred before tooth brushing. Saliva specimen can be added to the

viral transport medium.¹⁶ Commercially available saliva sampling devices and their company names can be accessed by all researchers, healthcare providers, doctors, microbiologists, and virologists for the handling of samples. Different saliva collection devices used in the sampling of contagious infectious diseases are Salivette® (Sarstedt); Quantisal® (Immunalysis); SCS® (Greiner-BioOne), VersiSAL®, and SuperSAL by Oasis Diagnostics® Corporation.⁶

The potential benefits of salivary diagnostic tests are economical, easier to apply than serum sampling with no requirement for specialized healthcare workers. Numerous samples are simple to obtain, collection and monitoring can be done at home with good storage than serum sampling. Saliva does not clot and can be handled more efficiently than blood with lesser agitation during the diagnostic process. Thereby, salivary diagnostic testing can offer a cost-effective and convenient mechanism for early-diagnosis of COVID-19.^{7,9}

Diagnostic kits and efficiency

Several viral infections can be diagnosed depending on the type of salivary biomarkers, such as viral DNA and RNA, antigens and antibodies. A quantitative real-time reverse transcription-polymerase chain reaction (RT-PCR) assay and fractionation experiment can detect the load of SARS-CoV.¹⁷ Nucleic acid extraction method, ELISPOT, POC technology can also be used to detect salivary biomarkers.^{7,14,18}

A study done by EPasomsub et al.(2020) investigated the diagnosis of COVID-19 and found the sensitivity and specificity of the saliva sample RT-PCR were 84.2%, and 98.9%, respectively.¹⁹ Hiba Hamid et al.(2017) concluded that POC technology using saliva can rapidly detect and effective in identifying and isolating potential carriers and contacts.¹⁸ Kelvin Kai-Wang evaluated that posterior oropharyngeal saliva sample contains the highest saliva load which can account for the fast spread of the infection.³ Anne L. Wyllie et al.(2020) described that saliva has greater detection sensitivity and consistency throughout the infection of COVID-19.

CONCLUSION

Saliva acts as a promising diagnostic tool in a large set of individuals requiring screening. This minimizes the load of collection of sample and nosocomial transmission of COVID-19 to the health workers. The possibility of the salivary glands as a reservoir, harboring latent infection, which may reactivate later, should also be considered and this warrants further research.

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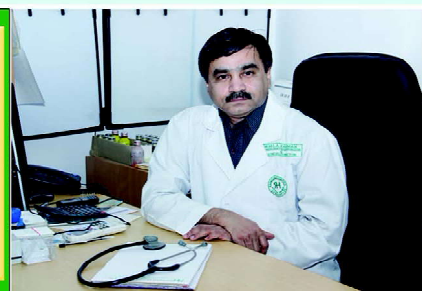
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